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DRAFT

ROCKY FLATS PLANT SITE-WIDE
QUALITY ASSURANCE PROJECT PLAN
FOR CERCLA REMEDIAL INVESTIGATIONS/FEASIBILITY STUDIES
AND
RCRA FACILITY INVESTIGATIONS/CORRECTIVE MEASURES STUDIES
ACTIVITIES

ENVIRONMENTAL RESTORATION PROGRAM
ROCKY FLATS PLANT
GOLDEN, COLORADO

ADMIN RECORD

A-SW-000374

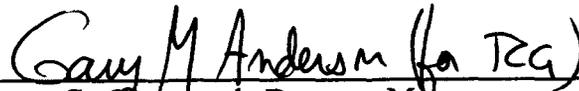
REVIEWED FOR CLASSIFICATION/UCM
By George H. Little
Date 8/24/90
[Signature]

This Quality Assurance Project Plan (QAPJP) is approved for implementation by the authority of the undersigned



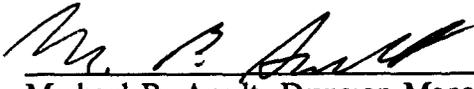
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EXECUTIVE SUMMARY

This "Rocky Flats Plant Site-Wide Quality Assurance Project Plan for CERCLA Remedial Investigations/Feasibility Studies and RCRA Facility Investigations/Corrective Measures Studies Activities" has been prepared pursuant to agreements made in the "Federal Facility Agreement and Consent Order" (IAG) dated December 1989 between the U S Department of Energy (DOE), the U S Environmental Protection Agency (EPA) and the Colorado Department of Health (CDH) In that agreement a "Sampling and Analysis Plan (SAP)" was to be prepared which would consist of a "Quality Assurance Project Plan" (QAPjP) and a body of "Standard Operating Procedures" (SOPs) The QAPjP is to describe the policy, organization, functional activities and quality assurance protocols necessary to achieve the data quality objectives dictated by the intended use of the data for each "Operable Unit" (OU) The QAPjP is required to consist of at least the following elements project description, project organization and responsibilities; data quality objectives, sampling procedures, detection limits, sample custody, calibration procedures, analytical procedures, data reduction, validation and reporting procedures, internal quality control and quality assurance procedures, performance and system audits, preventive maintenance requirements, data assessment procedures, corrective actions, quality assurance reports and measures outlined in Guidance for Conducting Remedial Investigations and Feasibility Studies under CERCLA, Interim Final, October, 1988 and Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans, QAM-005/80, U.S. EPA, 1983

In addition to the elements specified in the IAG and guidance documents, some ANSI/ASME NQA-1 elements have been added to facilitate implementation of the QA plan Figure 2-1 shows where each of the QA elements specified in EPA QAM-005 can be found in this QAPjP

This QAPjP describes the site-wide QA requirements which shall be implemented by the DOE, Rocky Flats operating contractor, EG&G Rocky Flats, Inc , and all subcontractors conducting response activities at the Rocky Flats Plant EG&G shall provide overall

management of the response effort, including subcontracted elements. In general, response activities are based on groupings of the hazardous waste sites identified as OUs which are made up of groupings of individual Solid Waste Management Units (SWMUs).

For specific response activities the EG&G Environmental Restoration Department and its subcontractors will propose site-specific Work Plan/Field Sampling Plans (WP/FSPs) and SOPs. Each WP/FSPs will include a "QA Addendum" (QAA) to this QAPjP, which will outline those detailed site- or project-specific data quality objectives, SOPs and specific measures taken to meet the QA requirements. For those WP/FSP/QAA activities which will require the participation of more than one participant, subcontractor or phased-in activities, a "Quality Summary Supplement" (QSS) will be prepared for each subcontractor outlining that participant's specific organizational structure and QA requirements under the QAPjP and site specific QAA. The QAPjP and the SOPs, referred to collectively as the "Sampling and Analysis Plan (SAP) in the IAG, and the WP/FSP/QAAs shall be submitted to both EPA and CDH for approval.

The goal of this site-wide QAPjP is to establish a QA program which will best help to provide verifiable scientific work and the management structure and attitude necessary to assure the data quality necessary to the decision-making process outlined in the IAG.

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STATEMENT OF POLICY

The Environmental Restoration (ER) Department endorses the application of solid quality management principles and recognizes the role of a coordinated Quality Assurance (QA) Program in helping to achieve its commitment to provide the highest quality scientific work. The goal of the ER Department QA Program is to select and implement those QA elements which best help to provide verifiable scientific work and the management structure and attitude necessary to foster an atmosphere of quality improvement. The achievement of quality is the responsibility of all personnel assigned to the ER Department and shall be accorded our top priority. The verification of the achievement of quality is the responsibility of the ER Department Quality Assurance Officer (QAO).

Full authority and organizational freedom is provided to the QAO by the ER Department Director to identify quality problems, identify or assist in recommending solutions, verify corrective actions, and exercise stop work authority for unacceptable activities or practices that may adversely affect quality.

This Quality Assurance Project Plan (QAPjP) establishes and presents the framework of requirements that shall be met in the planning, accomplishment, documentation, and verification of Environmental Restoration activities.

J E. Evered
Director
Environmental Restoration Department

SUMMARY OF REVISIONS

Major additions, deletions, and/or other changes to this QAPjP, since its last issued revision, which require substantive alteration procedures and actions, shall be summarized in this space in subsequent revisions. Such revisions will be noted by a horizontal bar in the margin.

ACRONYMS AND ABBREVIATIONS

ARAR	Applicable or Relevant and Appropriate Requirements
ASME	American Society of Mechanical Engineers
CAA	Clean Air Act
CAR	Corrective Action Report
CDH	Colorado Department of Health
CERCLA	Comprehensive Environmental Recovery and Compensation Liability Act
CHWA	Colorado Hazardous Waste Act
C-O-C	Chain-of-Custody
CLP	Contract Laboratory Program
DOE	U S Department of Energy
DQO	Data quality objectives
EMAD	Environmental Monitoring and Assessment Division
EPA	U S Environmental Protection Agency
ER	Environmental Restoration
ERD	Environmental Restoration Department (Rocky Flats)
FS/CMS	Feasibility Study/Corrective Measures Study
GRRASP	General Radiochemistry and Routine Analytical Services Protocol
HMWM	Colorado Department of Health Hazardous Materials and Waste Management Division
IAG	Federal Facility Agreement and Consent Order (Interagency Agreement)
IRA/IM	Interim Remedial Action/Interim Measures
M&TE	Measuring and test equipment
NCP	National Contingency Plan (of CERCLA)
NCR	Nonconformance Report
NEPA	National Environmental Policy Act
NIST	National Institute for Standards and and Technology [formerly known as the National Bureau of Standards (NBS)]
OSHA	Occupational Safety and Health Administration

OU	Operating Unit
PARCC	Precision, accuracy, representativeness, comparability, and completeness
PCB	Polychlorinated Biphenyl
QA	Quality Assurance
QAA	Quality Assurance Addendum
QAMP	Quality Assurance Management Plan
QAO	Quality Assurance Officer
QAPjP	Quality Assurance Project Plan
QC	Quality Control
QSS	Quality Summary Supplement
RCRA	Resource Conservation and Recovery Act
RFI/RI	RCRA Facility Investigation/Remedial Investigation
RFP	Rocky Flats Plant
RI/FS	Remedial Investigation/Feasibility Study
SAP	Sampling and Analysis Plan
SARA	Superfund Amendments and Reauthorization Act
SOP	Standard Operating Procedure
SOW	Statement of Work
SWMU	Solid Waste Management Unit
TCL	Target Compounds List
TAL	Target Analyte List
VOC	Volatile Organic Compound
WP/FSP	Work Plan/Field Sampling Plan

INTRODUCTION AND SCOPE

QA Project Plan Purpose

The purpose of this Quality Assurance Project Plan (QAPjP) is to identify the Quality Assurance (QA) requirements, and specific measures for implementing these requirements, that are applicable to the quality-affecting investigation and remediation activities at locations on the Rocky Flats Plant (RFP) site (Collectively, these activities will be referred to as "environmental restoration" [ER] activities) The locations requiring investigation and potential remediation are identified and agreed to in the draft "Federal Facility Agreement and Consent Order" (IAG), dated December 1989, between the U S Department of Energy (DOE), the U S Environmental Protection Agency (EPA), and the Colorado Department of Health (CDH) The level of detail in this QAPjP takes into consideration the potential for environmental releases, potential regulatory concerns, DOE orders, environmental laws, EPA guidance, and public visibility

QA Project Plan Scope

This QAPjP is applicable to RFP Comprehensive Environmental Response and Compensation Liability Act (CERCLA) Remedial Investigation/Feasibility Studies (RI/FS) and Resource Conservation and Recovery Act (RCRA) Facility Investigations/Corrective Measures Studies (RFI/CMS) for the operable units identified for investigation and potential remedial action as outlined in the draft IAG

Basis for Response Activities

Included in Attachment 2 of the IAG is the "Rocky Flats Plant US DOE Federal Facility Agreement Statement of Work" (IAG SOW) which sets forth elements of work required to be performed during the investigation and study phase of the response process As stated in the IAG SOW, "All response activities performed by DOE and its operating contractor, EG&G,

and EG&G subcontractors will be consistent with CERCLA, the National Oil and Hazardous Substances Contingency Plan (NCP), RCRA, and applicable State law. At a minimum, all response activities shall also be consistent with

- o Guidance for Conducting Remedial Investigation and Feasibility Studies under CERCLA, Interim Final, October 1988
- o RCRA Facility Investigation Guidance, Interim Final, May 1989
- o Guidance on Preparing Superfund Decision Documents The Proposed Plan and Record of Decision, March 1988
- o Test Methods for Evaluating Solid Waste Physical/Chemical Methods, SW-846, October 1986
- o Compendium of Superfund Field Operation Methodology, September 1987
- o Superfund Public Health Evaluation Manual, October 1986 [1]
- o Community Relations in Superfund A Handbook, Interim Final, June 1988
- o Federal Register, Volume 52, Number 53, Thursday, March 19, 1987, pp 8704-8709
- o Risk Assessment Guidance for Superfund, Volume II - Environmental Evaluation Manual, Interim Final, March 1989 "

¹The Superfund Public Health Evaluation Manual has been superceded by a two volume, interim final, risk assessment guidance. Volume II, Environmental Evaluation Manual is referenced in Appendix A. For assessment of human risk, Volume I, the Human Health Evaluation Manual should now be used. This document should be referenced instead of the PHEM if allowed by the IAG.

The IAG goes on to state that, "The most recent version of the above referenced citations are to be used "

The IAG SOW also states that, "While the statement of work (SOW) provides details in specific response requirements that must be met during the investigating and study phase of the response process, it is incumbent upon DOE to perform all response activities in compliance and consistent with the Federal Facility Agreement and Consent Order and applicable laws, regulations and guidance "

Basis for QA Requirements

In addition to the above, QA requirements have been identified, primarily based on guidance elements included in EPA QAMS/005/80, Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans, and the guidance documents referenced in the IAG Selected guidance elements from DOE 5700 6B and ASME NQA-1 have been included in this document to more completely describe the applicability of QA management controls over a given program area The basis for the QA requirements included in this QAPjP are discussed in further detail in Section 2.1.

Project Description

The RFP is located in northern Jefferson County, Colorado, approximately 16 miles northwest of downtown Denver (See Figure 1) The plant consists of approximately 6,550 acres of federally owned land in Sections 1 through 4 and 9 through 15, of T2S, R70W, 6th principal meridian Major buildings are located within a security area of approximately 400 acres. The security area is surrounded by a buffer zone of approximately 6,150 acres

The RFP is a government-owned, contractor-operated facility It is part of DOE's nationwide nuclear weapons research, development, and production complex and is administered by DOE's Rocky Flats Office. The management and operating contractor for

the RFP is EG&G Rocky Flats, Inc. The facility manufactures components for nuclear weapons and has been in operation since 1951. RFP fabricates components from plutonium, uranium, beryllium, and stainless steel. Production activities include metal fabrication, machining, and assembly. Both radioactive and nonradioactive wastes are generated in the process. Current waste handling practices involve on-site and off-site recycling of hazardous materials and off-site disposal of solid radioactive materials at other DOE facilities.

The RFP is currently regulated under the Colorado Hazardous Waste Act (CHWA) for treatment, storage, and corrective action, and is an interim status hazardous waste treatment/storage facility. In the past, both storage and disposal of hazardous and radioactive wastes occurred at on-site locations.

Description of Response Activities

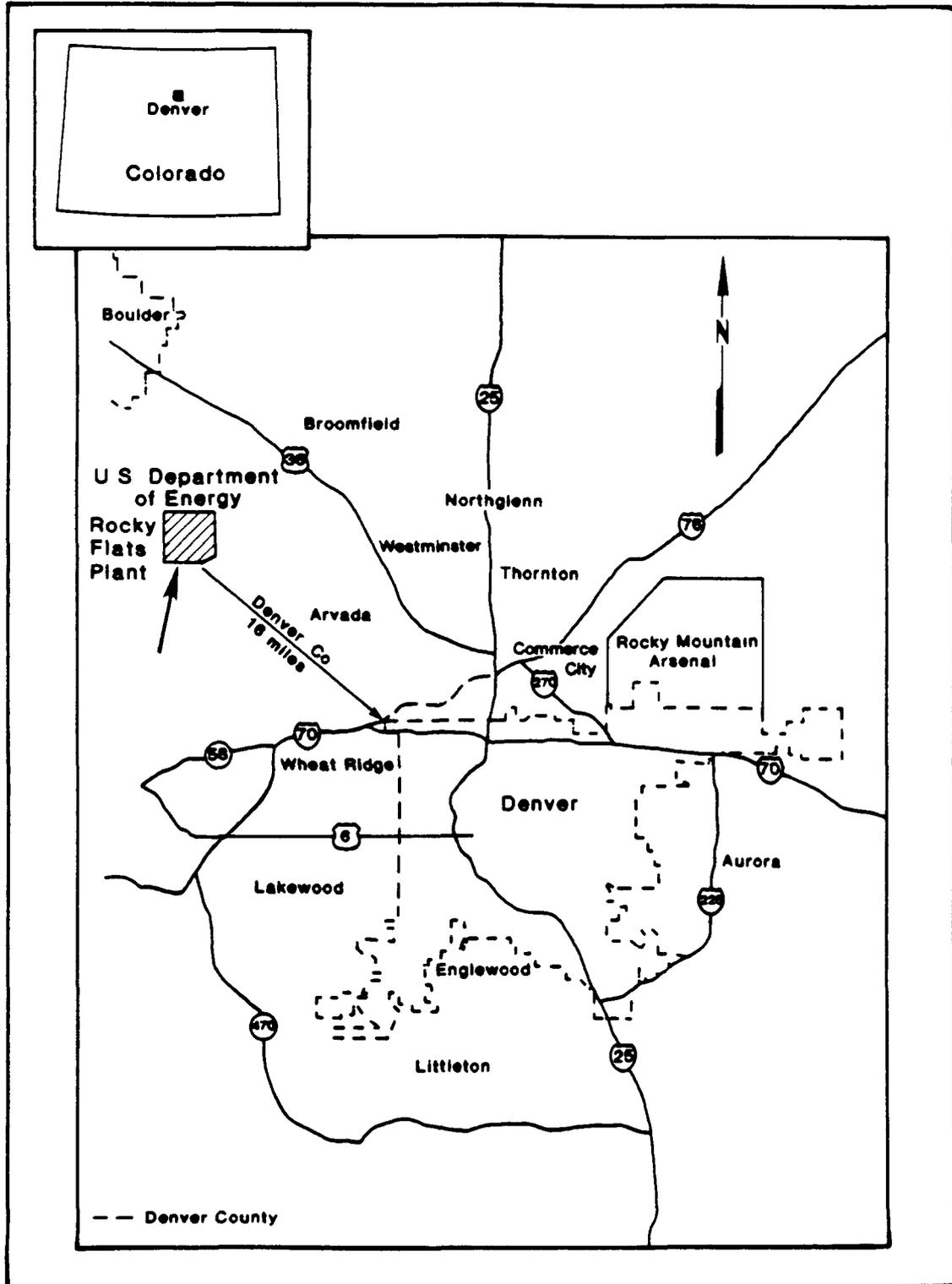
Activities performed by the Environmental Restoration (ER) Department which fall under the scope of this QAPjP include but are not limited to:

- o CERCLA Remedial Investigations (RI) to identify, confirm, and quantify contamination, and Feasibility Studies (FS)
- o Installation of environmental monitoring systems
- o RCRA Section 3004(u) actions associated with Solid Waste Management Units (SWMUs) that would meet the definition of past disposal sites under the ER Program
- o Interim Remedial Action/Interim Measures (IRA/IM)
- o RCRA Facility Investigations/Corrective Measures Studies (RFI/CMS)

- o Risk Assessments

- o Environmental Assessments

Figure 1
LOCATION OF THE ROCKY FLATS PLANT



1.0 ORGANIZATION AND RESPONSIBILITIES

1.1 PURPOSE

This section describes the organization and authority for the development, implementation, and verification of the Environmental Restoration (ER) Department Quality Assurance (QA) Program

1.2 APPLICABILITY

This section is applicable to all ER Department and subcontractor personnel performing activities for the Department

1.3 ORGANIZATIONAL STRUCTURE AND RESPONSIBILITIES

Organizational structure and responsibility of assignments have been established to obtain the following objectives

- o Achievement and maintenance of quality by those who have been assigned responsibility for performing the work (This includes those checks and approvals by other line personnel necessary to give confidence of results.)
- o Verification of overall quality by qualified persons or organizations not directly responsible for performing the work

The overall organization of EG&G Rocky Flats organizations involved in ER activities is shown in Figure 1-1 Figure 1-2 shows the organization of the ER Department Individual responsibilities are described below

Figure 1-1
Rocky Flats Organization
Involved with Environmental Organization

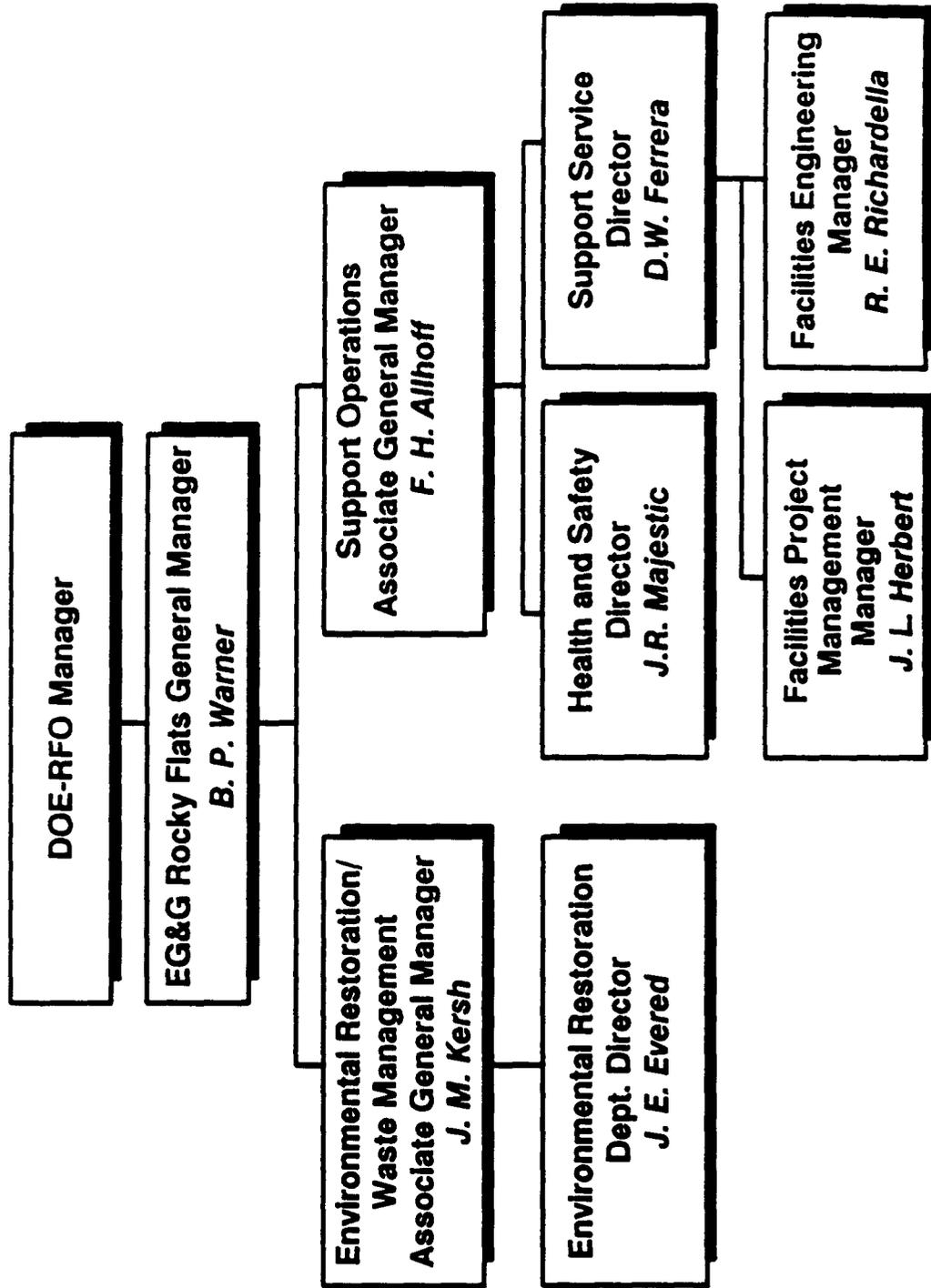
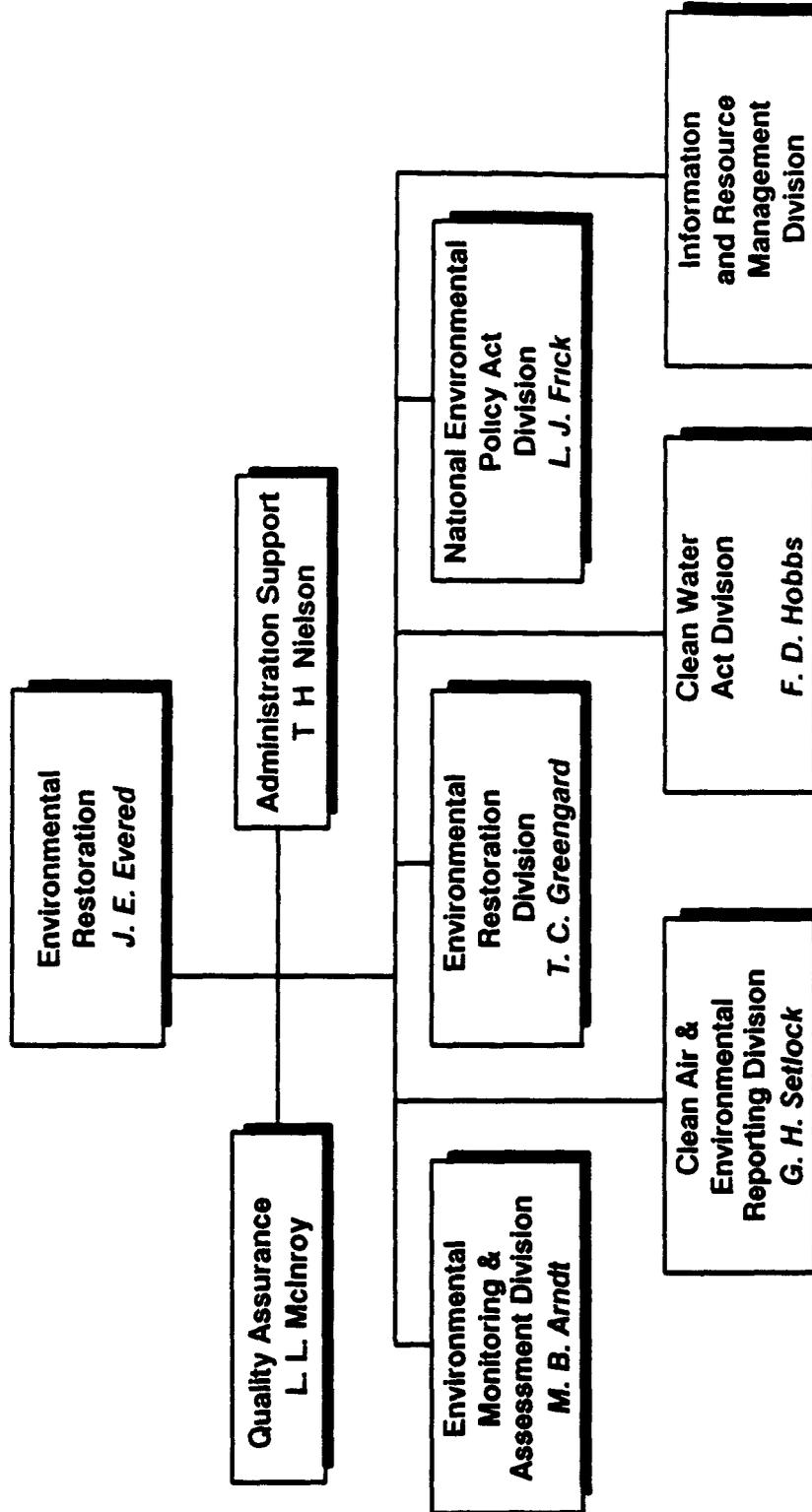


Figure 1-2
Rocky Flats Organization
Environmental Restoration Department



1.3.1 Director, Environmental Restoration Department

The ER Department Director's responsibilities include

- o Directing overall Department activities, including the establishment and execution of the QA Program and the assignment of an independent Quality Assurance Officer (QAO) with sufficient authority, access to work areas, personnel, and cost, schedule, and organizational freedom
- o Assuring the development of administrative or standard operating procedures as necessary which specify how the QAPjP requirements are to be implemented, and assuring the implementation of requirements in this QAPjP for all quality-affecting activities
- o Directing corrective actions and resolution of differences of opinion between the QAO and other personnel involved in ER activities
- o Approving procedures, instructions, and plans issued at the Department level
- o Determining, in consultation with the QAO and Division Managers, those documents which require distribution control
- o Assuring internal verification of QA Program implementation through audits, surveillance, management assessments, and internal and peer reviews
- o Assuring that only properly trained and qualified/certified personnel are used (as applicable) to perform ER Department activities This particularly applies to inspectors and auditors

- o Assuring that nonconforming items are properly identified, segregated, and/or marked to prevent inadvertent use, and dispositioned in accordance with documented procedures
- o Assuring that significant conditions adverse to quality are identified, evaluated, and properly dispositioned to include identification of root cause(s) and approving proposed corrective actions
- o Assuring the development and implementation of procedures for the control of software used by ER Department to develop results that will be reported to regulators and others
- o Establishing, staffing, and directing a document control and records management system

1.3.2 Quality Assurance Officer

The QAO's responsibilities include

- o Providing guidance and consultation for implementing QA Program requirements
- o Directing the QA activities of the ER Department and the development, maintenance, and verification of the ER Department QA Program.
- o Reviewing procurement documents to ensure applicable QA Program elements have been passed on to suppliers and subcontractors
- o Reviewing the QA Project Plan, Quality Assurance Addenda (QAAs), Quality Summary Supplements (QSSs), procedures, instructions, and test plans with respect to quality assurance

- o Overseeing QA Records system
- o Providing training in the requirements of this QAPjP and related topics, such as quality assurance theory and practice
- o Assuring that appropriate contractor/vendor surveillances and compliance audits are performed
- o Verifying that inspections and tests are performed as appropriate and that inspection/test personnel are properly qualified/certified
- o Assuring that Measuring and Test Equipment (M&TE) used in ER quality-affecting activities is controlled and calibrated
- o Verifies that necessary audits and surveillances of sample handling, storage, and shipping are performed
- o Developing quality verification activity schedules
- o Selecting, training, and certifying audit personnel and other quality verification personnel
- o Reporting the results of quality verification activities to the ER Department Director and others as appropriate.
- o Concurring with Nonconformance Reports (NCR) dispositions, and maintaining a system for tracking and trending NCRs
- o Monitoring corrective action documentation for conditions adverse to quality, investigating and validating corrective action reports, verifying implementation of

corrective actions, tracking and trending corrective action status, and closure of corrective action documentation upon satisfactory completion of corrective action

1.3.3 Environmental Restoration Department Division Managers

The responsibilities specific to each division are outlined in the ER Department Division Charters. In general, the ER Department Division Managers' or designee's responsibilities include

- o Assignment and supervision of Group Managers
- o Assuring that personnel are qualified and trained as appropriate
- o Performing periodic management assessment of QA Program implementation and effectiveness
- o Designating a Technical Point-of-Contact (POC) for major procurement and subcontract activities
- o Approving procedures, instructions, plans, and their revision at the Division level
- o Assigning a Quality Coordinator for the Division
- o Establishing controls on analytical and monitoring processes to assure processes are maintained within acceptable limits and that valid data quality levels are maintained
- o Assuring the development and approval of test plans, overseeing testing activities, and ensuring that test results are properly documented

- o Assuring that M&TE used in the collection of data are properly calibrated and that measurements performed with M&TE that was out of calibration are reported to the QAO
- o Providing input into quality verification schedules, and assuring the availability of personnel participating in these activities
- o Concurring with the dispositions and corrective actions identified in NCRs and assuring that nonconforming conditions are immediately addressed
- o Assuring that personnel generate, process, validate, maintain, classify, and disposition QA Records in accordance with the requirements of this QAPjP
- o Assuring that the retention period of their QA records are identified
- o Assuring the development and approval of software development requirements and assuring software validation and verification prior to use

1.3.4 Procurement Department Personnel

Procurement Department personnel responsibilities include

- o Processing purchase requisitions/contracts to meet EG&G standards, policies, and practices.
- o Assuring that changes are not made to the technical or QA requirements without written consent from the ER Department Division Managers, or delegates, and QC
- o Submitting procurement records to records management personnel

1.3.5 Document Control and Records Management Personnel

Document control and records management personnel responsibilities include

- o Developing and maintaining a document control and records management system
- o Issuing the controlled documents to recipients identified on distribution lists
- o Assuring that revised documents are identified according to their revision status, superseded, or destroyed

1.3.6 Technical Point-of-Contact

The designated procurement/subcontract Technical POC is responsible for

- o Acting as the EG&G technical liaison with the supplier or subcontractor
- o Initiating acceptance of items or services to assure that they meet procurement document requirements or that appropriate nonconformances are documented and corrective actions are taken

1.3.7 Environmental Restoration Department and Division Personnel

ER Department personnel responsibilities include

- o Implementing operational procedures for their assigned tasks and the requirements in this QAPjP
- o Promptly reporting conditions adverse to quality to line management and the QAO when discovered

1.3.8 Quality Coordinators

Quality Coordinators are responsible for

- o Coordinating QA Program activities within their ER Department Divisions
- o Providing guidance to other personnel in meeting QA Program requirements
- o Assuring that QAPjPs, QAAs, QSSs, procedures, instructions and test plans specific to the division are developed, approved, and implemented
- o Maintaining direct communication and liaison with the ER Department QAO and direct line authority in conjunction with the Division Manager for the implementation of the QA Program within their Division

2.0 QUALITY ASSURANCE PROGRAM

2.1 QA PROJECT PLAN BASIS

The QA functions outlined in this Quality Assurance Project Plan (QAPjP) have been developed under U S Environmental Protection Agency (EPA) guidance for preparing QAPjPs, contained in EPA/QAMS/005/80, Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans, guidance documents referenced in the IAG SOW, and U S Department of Energy (DOE) Order 5700 6B, Quality Assurance, 1986, and DOE Quality Assurance Requirements for Rocky Flats Management and Operations, 1990 This QAPjP format is grouped into 19 sections based on the 18 criteria in the DOE RFP QA Requirements Document and with elements of EPA/QAMS/005/80 accommodated within those sections A matrix identifying where the elements of EPA/QAMS/005/80 are addressed in this QAPjP is shown in Figure 2-1

This QAPjP describes the QA requirements which shall be implemented by the DOE, the Rocky Flats operating contractor, EG&G Rocky Flats, Inc , and all subcontractors conducting response activities at the Rocky Flats Plant (RFP) EG&G shall provide overall management of the response effort, including subcontracted elements and subcontractors In general, response activities are based on groupings of the RFP hazardous waste sites which are identified as Operable units (OUs) made up of groupings of individual Solid Waste Management Units (SWMUs)

2.2 QA PROJECT PLAN FORMAT

With the exception of Sections 1 and 2, this QAPjP is formatted using the following method Each section contains a discussion of the section's purpose, applicability, requirements, and QA records required to be maintained as a result of implementing the requirements.

Figure 2-1

LOCATION OF QAMS-005/80 ELEMENTS WITHIN THE RI/FS QAPjP

<u>EPA QAMS-005/80 ELEMENT</u>	<u>QAPjP SECTION</u>
(1) Title Page with Approvals	Title and Approvals
(2) Table of Contents	T of C
(3) Project Description	Intro and Scope
(4) Project Organization and Responsibility	1 0
(5) Data Quality Objectives (DQOs)	3 3 1
(6) Sampling Procedures	3 3 6 and 5 3 1
(7) Sampling Custody	8 0
(8) Calibration Procedures and Frequency	12 3 3 and 12 3 4
(9) Analytical Procedures	3 0
(10) Data Reduction, Validation, and Reporting	3 3
(11) Internal Quality Control Checks and Frequency	3 3 10
(12) Performance and System Audits and Frequency	18 3
(13) Preventive Maintenance Procedures and Schedules	12 3 5
(14) Specific Routine Procedures to Assess Data Quality	3 1
(15) Corrective Action	16 0
(16) Quality Assurance Reports to Management	2 6

2.3 QAPjP RELATIONSHIP TO WORK PLAN/FIELD SAMPLING PLAN

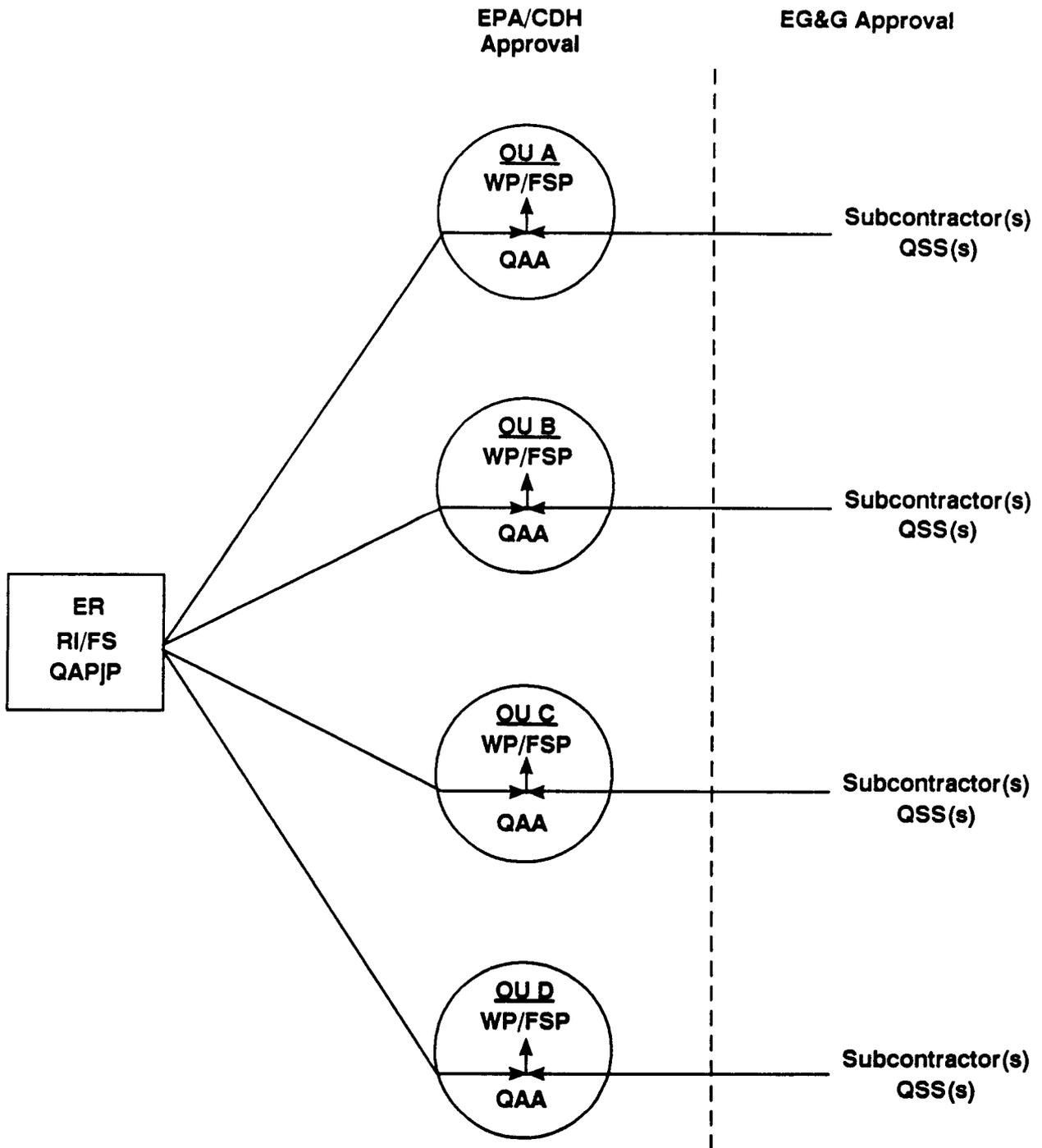
The ER Department and its subcontractors will propose site-specific Work Plan/Field Sampling Plans (WP/FSPs) and Standard Operating Procedures (SOPs) which will include provisions for meeting the requirements and work specified in the IAG. Each WP/FSPs will include a "QA Addendum" (QAA) prepared under the direction of the ER Department which will outline those site- or project-specific measures taken to meet the QA requirements in this QAPjP. In addition, a "Quality Summary Supplement" (QSS) will be prepared for each subcontractor conducting WP/FSP activities, outlining their organization and the specific measures to be implemented to meet the QAPjP and QAA objectives. The relationship of the QAA and QSS to this QAPjP is shown in Figure 2-2. The content and instructions for preparing the QAA and QSS are described in an SOP.

This QAPjP and the SOPs, referred to collectively as the "Sampling and Analysis Plan (SAP) in the IAG," shall be submitted to both the EPA and Colorado Department of Health (CDH) for approval as specified in the IAG. The WP/FSPs which will be prepared for each OU and selected site-wide activities such as environmental evaluation and possibly the treatability studies shall include the QAAs, SOPs and SOP addenda, and shall also be submitted to EPA and CDH for approval. QSSs which identify the responsible subcontractor organization and the measures to be taken to achieve the QA requirements stated in the WP/FSP QAA shall become a part of the RFP QA Record.

2.4 TRAINING, QUALIFICATION, AND CERTIFICATION

Personnel involved in activities affecting quality shall receive appropriate training and orientation from qualified personnel to assure proper understanding of the requirements of this QAPjP and supporting procedures prior to initiation of quality-affecting activities. Specialized training and orientation shall be provided to assure that personnel, including quality verification and inspection personnel, achieve and maintain suitable proficiency in the activities they perform.

Figure 2-2
QAPjP/QAA/QSS Relationship



The ER Department Division Managers shall assure that training needs and assignments are developed. They shall also review and approve assignments. Completion of training activities shall be documented. The QAO shall assure that appropriate training is provided. Training may be provided in the form of required reading, formal classroom sessions, on-the-job training, or other methods. Division Managers shall assure that assigned staff receive complete training commensurate with the scope and complexity of their assigned tasks.

2.4.1 Personnel Training

Project personnel shall be trained in their areas of responsibility. With respect to QA activities and procedures, key project personnel shall be provided an orientation session on the QA requirements contained in the QAPJP. Attendance at the orientation shall be documented using an Orientation Attendance Sheet, Figure 2-3.

ER Department and subcontractor personnel conducting ER field activities are also required to complete the Occupational Safety and Health Administration (OSHA) 40-hour Hazardous Waste Site Worker Safety Training and the annual OSHA 8-hour Hazardous Waste Site Worker Safety Refresher course (required by 29 CFR 1910.120). In addition, personnel directly supervising hazardous waste site workers are required to complete the OSHA 8-hour Hazardous Waste Site Supervisor Safety course.

Site safety training consistent with the requirements found in the Site Health and Safety Plan shall also be conducted. Project participants who perform activities for this project shall be trained in the applicable safety procedures.

2.4.2 Qualification and Certification of Personnel

The QA Officer shall assure that an appropriate personnel qualification system is developed. Division Managers are responsible for assuring that personnel performing quality-affecting activities are properly qualified and certified, as necessary, as identified in job descriptions.

Division Managers shall assure that documentation is available which verifies that the education and experience required for these positions have been met

2.4.3 Proficiency Evaluation

Supervisory personnel shall assure that the job proficiency of personnel performing quality-affecting activities is monitored, and documented at least annually, according to an established personnel qualification system

2.5 SUBCONTRACTOR/VENDOR QA PROGRAM

Applicable elements of the QA Program described in this QAPjP and supporting procedures shall be passed on to subtier organizations, such as subcontractors and vendors, through procurement and contracting documents

2.6 QUALITY ASSURANCE REPORTS TO MANAGEMENT

The ER Department Director, Division Managers, and the QAO shall rely on written reports documenting project progress and status, with respect to quality data assessment activities, system and performance audits, corrective action reports, ad hoc QA status summaries, and technical memoranda, to ensure overall adherence of the project to QA requirements

The QAO will provide guidance to the Division Managers and their staff in the review of QA reports, including those prepared by Division Quality Coordinators or subcontractor QA staff, and will provide recommendations to the ER Department Director and Division Managers concerning any QA actions that need to be taken. The QAO will verify preparation of Corrective Action Reports resulting from surveillance activities, audits, progress reports, or documentation of any problems requiring corrective action. The QAO may generate some of these reports or direct Division Quality Coordinators or QA

subcontractors in preparing them The reports shall be maintained in the QA records management system

3.0 DESIGN CONTROL

3.1 PURPOSE

This section describes the requirements and methods by which design functions for scientific investigations, analysis, and report preparation, are controlled and verified by the Environmental Restoration (ER) Department Divisions

The design controls include requirements for the establishment of data quality objectives, sampling procedures, data reduction, validation, and reporting, internal quality control checks, data assessment, data validation criteria, peer review, and design records

3.2 APPLICABILITY

Design control requirements are applicable primarily to scientific investigations, which include field sampling, sample and data handling, and analysis and interpretation, as required under the IAG and referenced guidance documents. This section is applicable to personnel performing work activities which affect the data quality required for those activities.

Plant facilities designed, engineered, or constructed which are specifically related to environmental restoration of plant areas, Operable units (OUs), Solid Waste Management Units (SWMUs), or Resource Conservation and Recovery Act (RCRA) Closure Units are not addressed in the requirements of this Quality Assurance Project Plan (QAPjP). Design control methods for these facilities are currently addressed in RFP Facilities Engineering and Project Management Manual, used to satisfy DOE Order 6430 1A

3.3 REQUIREMENTS

3.3.1 Data Quality Objectives

Data quality objectives quantitatively and qualitatively describe the uncertainty that a decision maker is willing to accept in results derived from environmental data. This uncertainty is used to specify the quality of the measurement data required, usually in terms of precision, accuracy, representativeness, comparability, and completeness.

The process for establishing project/site specific DQOs is described in EPA/540/G-87/003, Data Quality Objectives for Remedial Activities - Development Process, and is outlined in Appendix A. An example DQO development scenario for RI/FS activities at a site with contaminated soils and groundwater is presented in EPA/540/G-87/004.

DQOs must be established prior to the initiation of field or laboratory work using the process described in Appendix A. The DQOs must be documented in the WP/FSP and summarized in the QAA.

3.3.2 Sampling Procedures

Approved SOPs, which will be identified in the SAP, QAAs and QSSs, outline specific sampling procedures for ER activities. SOP Addenda (SOPAs) may be utilized to incorporate desired variations into standard SOPs. SOPs and SOPAs will be incorporated into the WP/FSPs for appropriate approvals. New procedures, if needed, may be submitted and/or recommended in the WP/FSPs on an individual basis. All requests for new or revised SOPs must be submitted to the appropriate Division Manager as specified in Section 5.0. The Division Manager, or his designee, will obtain the required approvals, including EPA/CDH approval, prior to use.

3.3.3 Data Reduction, Validation, and Reporting

Analytical data results will be submitted to the ER Department Environmental Monitoring and Assessment Division (EMAD). These data will include results from field surveys and laboratories. Analytical results will be independently validated and the results will be submitted to the EMAD. EMAD will review DQOs specified in the WP/FSPs to determine if existing analytical and validation guidelines will address validation needs. If validation guidelines do not address DQO needs, the existing guidelines will be revised or new guidelines will be developed.

3.3.3.1 Data Reduction

Data reduction functions are divided into field and laboratory reduction activities. Each of these activities are summarized below.

Field Data Reduction

Field measurements, data, and observations will be recorded in project log books, on field data forms, or on similar permanent records. Entries will be recorded directly and legibly in indelible ink in field logbooks or on field forms with all entries signed and dated, or as specified in SOPs (note for some field measurements, this may not be appropriate, [i.e., seismic logs, strip charts], accepted standard methods specific to these activities will be used). If entries must be changed, the change will not obscure the original entry. The reason for the change will be stated and the correction and explanation will be signed and dated or otherwise appropriately identified at the time the correction is made. Field data records will be organized into standard formats whenever possible and retained in the QA records system. Field operations and sampling records include but are not limited to

- o Field data sheets and field logs
- o Data processing and storage records

- o Sample identification and chain-of-custody (C-O-C) records
- o Document control, inventory, and filing records
- o QA/QC records
- o Health and safety records

The combined data records will be sufficiently detailed to provide a complete and accurate history of data gathering and results

Laboratory Data Reduction

Laboratory data will be recorded or acquired during analysis and then prepared for review through computerized or manual algorithms to produce a raw data set (note the General Radiochemistry and Routine Analytical Services Protocol specifies the use of "flat" ASCII format) Raw data will be verified in the laboratory through checking calculations, dilutions, and standard QC sample concentrations and comparing these to known or expected values Any errors or discrepancies discovered during reduction will be resolved through the use of "Nonconformance Procedures" referenced in Section 15 prior to generating final reports Corrections to raw data and documentation will be initialed and dated after making the changes A second verification of laboratory data reduction will occur during data validation

3 3 3 2 Validation

Validation activities consist of reviewing and verifying field and laboratory data and evaluating data quality The field and laboratory validation activities are described below Data validation includes the analytes listed in the RFP-SOW GRRASP and specific validation guidelines DQOs are listed in the WP/FSP/QAAs which are provided to the EMAD.

Field Data Validation

Validation of field technical data will be performed on two different levels. First, all data will be validated by periodic surveillances at the time of field collection by following RFP SOPs for data validation. Secondly, data will be validated by the EMAD or field data validation subcontractor who will review all collected data to ensure the correct codes and units have been used. After the data has been reduced, the field data validation subcontractor will review data sets for anomalous values. Any inconsistencies discovered will be annotated by data validation personnel in the field log book to explain any anomalous values.

Random checks of sampling and field conditions (e.g., weather, wind, temperature, etc.) will be made by the field data validation subcontractor, the appropriate ER Department personnel, as well as other QA/QC personnel, who will check recorded data to confirm observations. Whenever possible, in-house peer review will also be incorporated into the data validation process in order to maximize consistency among field personnel. EMAD will validate field data prior to inclusion into the RFED database using validation guidelines and the DQOs established in the WP/FSP/QAAs.

Laboratory Data Validation

Laboratory data will be reviewed and validated by the EMAD laboratory validation subcontractor. Results of data review and validation activities are documented in data validation reports. EPA-CLP data validation functional guidelines are used for validating organic and inorganic (metals) data. Functional guidelines for validating most radiochemistry and water quality parameter data have not been published by EPA, however, data validation functional guidelines, applied directly from EPA-CLP, have been established by the EG&G ER Department. The functional guidelines which will be used to evaluate analytical data are the following:

- o U S EPA, Laboratory Data Validation Functional Guidelines for Evaluating Organics Data (2/88)
- o U S. EPA, Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Data (7/88)
- o EG&G Rocky Flats, Water Quality Parameter Data Validation Guidelines (9/89, Rev 3/90)
- o EG&G Rocky Flats, Radiochemical Data Validation Guidelines - Tritium Analyses by Liquid Scintillation (9/89, Rev 5/90)
- o EG&G Rocky Flats, Radiochemical Data Validation Guidelines - Isotopic Analyses by Gamma Spectrometry (9/89, Ref 5/90).
- o EG&G Rocky Flats, Radiochemical Data Validation Guidelines - Gross Alpha/Beta by Gas Proportional Counters (9/89, Rev 5/90)
- o EG&G Rocky Flats, Radiochemical Data Validation Guidelines - Isotopic Analyses by Alpha Spectrometry (draft 7/90)
- o Accepted standard or approved validation guidelines

Analytical data generated for ER Program activities are assigned data usability qualifiers
Data usability qualifiers are assigned as a result of the data validation process and are
consistent with EPA data usability qualifiers

- V Valid (usable for all purposes)
- A Acceptable with qualifications (usable for most purposes).
- R Rejected (unusable for most purposes)

All data generated in conjunction with IAG specified activities are subject to verification and validation, or as agreed to between DOE/CDH/EPA. Data review and validation needs are referenced in the GRRASP. Other data review and validation needs will be specified in the WP/FSP/QAAs and supporting SOPs.

3 3 3 3 Reporting

Results of data validation are reported in ER Department Data Assessment Summary reports, which are prepared by ER Department subcontractors and submitted to the EMAD. Sample analysis reporting turnaround times are presented in Table 3-1. The reporting frequencies have been established for ER routine analyses. Reporting times for some analyses may be accelerated.

Table 3-1
Analytical Reporting Turnaround Times
CLP
(Calendar Days)

<u>Analysis Package</u>	<u>Sample Data Diskette</u>	<u>Supporting Data Documentation</u>
All except Radiochemistry	45 days	50 days
Radiochemistry	61 days	66 days

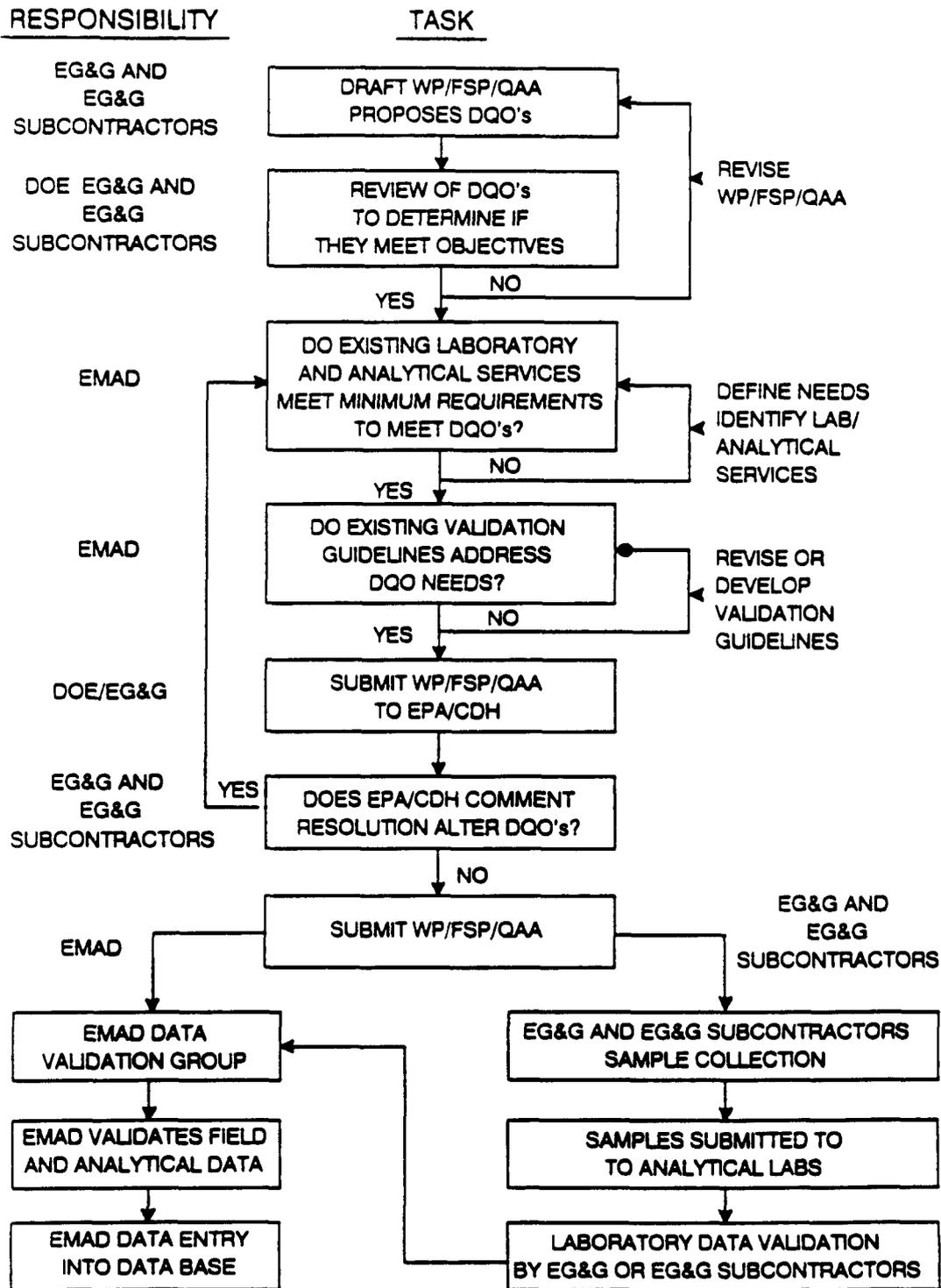
EMAD and the validation subcontractor receive analytical results as soon as they are available. The validation subcontractor validates the data and submits the validated data within 30 days to EMAD. Figure 3-1 illustrates the validation process.

3.3.4 Internal Quality Control Checks

Standard QC procedures are employed to provide accurate, precise, consistent, and comparable results. QC procedures consist of field QC samples and laboratory QC samples. For analyses under the GRRASP, the contract laboratories will provide field contractors with sample bottles which are equivalent to I-Chem 300-series (I-Chem brand bottles are not required). Any field preparation of the sample bottles will be in accordance with approved SOPs.

Figure 3-1

Validation Process



3 3 4 1 Field Sampling Quality Control Procedures

The field duplicate, the trip blanks, and the equipment rinsate blanks, where appropriate, will be sent from the field with the samples to the analytical laboratories. Other QC techniques may be employed with geotechnical or geophysical data where replicates or blanks are not practical. Table 3-3 shows general guidelines used for the collection frequency of QC samples outlined in the GRRASP Procedures which describe duplicate, trip blank, and equipment rinsate blank preparation for field sampling quality control are described in Section 5.0 of Standard Operating Procedures, Environmental Restoration Program, Rocky Flats Plant (1/89)

Table 3-3
QC Sample Collection Frequency

<u>Activity</u>	<u>Frequency</u>
Field Duplicate	1 in 20
Trip Blank	1 per shipping container
Equipment Rinsate Blank	1 in 20
Other QC Activities	As specified in the WP/FSP/QAA

The field replicates and blanks will be used to provide measures of the internal consistency of the sampling procedures and storage practices. For analyses conducted under the GRRASP, the total number of QC samples that will be collected will represent at a minimum one for every batch of 20 field samples. This proportion of QC samples will identify most

potential sources of error Applicability and need for QC samples for other samples (e g , geologic, biological) will be addressed in DQOs in the WP/FSP/QAAs and SOPs

3 3 4 1.1 *Field Duplicate*

A field duplicate is typically obtained when a sample from one location is split into two equal portions, with each portion going to the laboratory in a separate container (Note Duplicate samples of volatiles will be collected to reduce the possibility of volatilization in the sample) The field duplicate will be collected using the same procedures as those used to collect a regular sample except that two identical samples will be collected For atmospheric samples, a field duplicate is obtained by a complete separate sample taken from a separate sampler Both samples will be analyzed identically

3 3 4 1 2 *Equipment Rinsate Blank*

Equipment blanks will be prepared for manual and small automated sampling equipment used to collect samples Equipment blanks will be collected once per every 20 samples by pouring volatile-free ASTM Type II reagent water into/through/over a decontaminated piece of sampling equipment (such as a bailer) and then dispensing it into prepared sample bottles Sample bottles will be randomly selected from the supply of prepared sample bottles, selecting a sample container appropriate for each type of analysis for which environmental samples are being collected Analyses of equipment rinsates are used to assess the efficiency of implementation of equipment decontamination SOPs The need for rinsate analyses will be specified in the WP/FSP/QAA

3 3 4 1 3 *Trip Blanks*

Trip blanks for water samples will be prepared prior to the sampling trip by pouring volatile-free ASTM Type II reagent water into prepared sample bottles These sample bottles will be randomly selected from the supply of prepared sample bottles. Sample containers will

be filled to yield an appropriate sample volume for each suite of VOC analysis, resulting in a complete trip blank for the sampling event. These trip blanks will be prepared at the laboratory, shipped to the site, stored with the unused sample bottles, and then shipped back for analysis with the samples collected during the sampling event. The trip blanks will remain unopened throughout the sampling event. Analysis of trip blanks is used to assess contamination of sample containers during storage at the site and contamination of samples during transport to the laboratory. One trip blank will be included in each shipping container containing samples for VOC analysis.

Trip blanks will be used when appropriate. Commercially available blank soils and solid materials that adequately reflect the various soil types encountered within each borehole are not available. Development of blank soil types within the RFP region is not practical due to the subjectivity of characterizing background soil conditions and the variability of soil conditions.

Field blanks for atmospheric data are taken to the field and exposed to handling and atmospheric conditions nearly identical to those for the samples themselves. The blanks are shipped with the regular sample shipment and are analyzed along with the regular samples.

Trip blanks for atmospheric samples will be shipped and stored in a manner identical to the regular sample media. They will not be exposed to environmental conditions. The trip blanks and field blanks can be analyzed to isolate the source of any suspected contamination.

3.3.4.2 Laboratory Quality Control Procedures

Laboratory QC procedures are used to provide measures of internal consistency of analytical and storage procedures. Specific QC procedures and QC criteria are in place for organic, inorganic, water quality parameter, and radiochemical analyses. The laboratory QC procedures used are described in detail in the analytical methods cited and in the GRRASP. All laboratory QC procedures shall be consistent with or equivalent to EPA-CLP QC.

procedures QC procedures for non-CLP methods will be developed using SW846 or other standard methods on an as-needed-basis For example, for continuous air and meteorological data, the EPA special guidance for these programs will be used

3.3.5 Data Assessment

EMAD is responsible for evaluating and validating analytical data from ER Department subcontract laboratories The EMAD staff may be assisted in this task by subcontractor personnel who provide data review and validation support In addition to validating data, the EMAD staff may assist the ER Department and subcontractor technical staff in determining data usability and acceptance

3 3 5 1 Calculations

To ensure defensibility of the records, calculations shall be legible and in logical progression so that the steps and the reasoning behind the calculations can be understood For calculations performed using a programmable calculator or computer, a sample calculation will be included in the permanent files together with a program listing and printout of input data The calculated results also shall be placed in the QA records system files A calculation or series of calculations shall contain the following, as a minimum

- o Task number, date performed, and signature of person who performed the calculation
- o Purpose for calculation.
- o Assumptions made or inherent in calculation.
- o Reference (including page, where applicable) for each piece of input data (e g , standard notebook, telephone memorandum, technical paper)

- o Method used for calculations

- o Results (underlined)

Calculations shall be spot checked by an independent engineer or scientist of professional level equal to or higher than that of the originator. After completing the check, the reviewer shall sign his or her name and the date immediately below that of the originator on the calculations. Both the originator and reviewer are responsible for the completeness and accuracy of the calculations and must initial any corrections or changes. This process certifies that the methodology or computer program is as expected.

3.3.5.2 Data Assessments

Data acceptance criteria and requirements are found referenced in the GRRASP, EPA data validation functional guidelines, EG&G internal data validation functional guidelines, and the DQOs. Analytical data will be assessed in two ways (1) validity and (2) usability. Data validity and usability are closely related and may be assessed as

- V Valid, usable for all purposes
- A Acceptable with qualifications, usable for most purposes
- R Rejected, unusable for most purposes

The quality, validity, and appropriate use of environmental measurement data collected for this project will be determined by the Data Users prior to use.

3.3.6 Data Validation Criteria

The levels of data quality are determined by evaluating the quality of the data in the following terms

- o data quality objectives (precision, accuracy, representativeness, completeness, comparability)
- o intended use of the data (monitoring, decision-making, risk assessment, etc)
- o specific agreements and/or regulatory requirements (detection limits, analytical methods, types of analyses, QC)

Three levels of data validity have been established for the ER activities at the RFP

- a Valid Data meets the following seven objective standards, where applicable
 - 1 analytical methods followed,
 - 2 acceptance criteria achieved,
 - 3 sufficient number and type of QC samples analyzed,
 - 4 QC limits achieved,
 - 5 compounds and analytes correctly identified,
 - 6 equipment/instrumentation calibration criteria achieved, and
 - 7 sample holding times met
- b Acceptable With Qualifications Data meets most, but not all, objective standards
All primary validation criteria are achieved within acceptable limits (calibration, QC limits, method requirements, compounds and analytes correctly identified)
- c Rejected. Data fails to meet objective standards or fails to meet primary validation criteria

The following three levels of data usability are utilized for the ER Program at the RFP

- a. Data is usable for all purposes if all of the following criteria are met

- Data quality is classified as valid
 - All data quality objectives are achieved
 - All specific agreements and/or regulatory requirements are met
- b Data is considered usable for some purposes if any of the following conditions occur
- Data quality is classified as valid or acceptable with qualifications (rejected data may be usable for some very limited purposes such as screening)
 - Not all data quality objectives are achieved
 - Not all specific program requirements are met
- c Data may be unusable if any or all of the following conditions are met
- Data quality is classified as rejected
 - Data quality objectives are not achieved
 - Specific program requirements not met

(Note: Rejected data will be identified and controlled as outlined in Section 8, Identification and Control of Items, Samples, and Data)

3.3.7 Peer Reviews

When ER activities involve state-of-the art or untried technologies, peer reviews of data, reports, conceptual designs, etc. will be performed. A peer review team will be appointed by the ER Department Director or appropriate Manager(s). The peer review team will consist of independent qualified experts. The review and approval of the team members' credentials, including verification of education and experience, will be documented by the appropriate ER Department management representative. Peer reviews will be documented and prepared by the peer review team leader, and approved by the ER Department.

management representative During the peer review, all review comments will be documented, as well as the resolution of all comments Dissenting opinions which cannot be resolved will also be clearly indicated

The original document, submitted for peer review comments, and resultant changes to the documents will be included in the document package and forwarded to the QA records management system

3.3.8 Design Records

Design documentation for scientific investigations, analyses, and report preparation, including the design bases, input documents, references, design decision documentation, including but not limited to memoranda, analyses, drawings, specifications, as-built drawings and records, other design output documents, evidence of design verification/evaluation, qualification records of reviewers, and documents confirming interface control, with approved changes thereto, shall be considered QA Records and controlled in accordance with Section 17 of this QAPJP

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 PURPOSE

This section defines the requirements and methods for the control of procurement documents associated with the purchase of items or services for the Environmental Restoration (ER) activities

4.2 APPLICABILITY

These methods are applicable to personnel who are involved with the procurement of items or services. The applicable implementation requirements from the "QA Plan for Procurement Requisitioners' ER Program" shall be applied to each ER Department purchase request or contract

4.3 REQUIREMENTS

The ER Department Division Managers, or delegates, shall initiate and maintain a procurement document package which includes provisions for the following, as deemed appropriate

- o Scope of work
- o EG&G technical requirements
- o Requirements, as outlined in the IAG and applicable guidance documents
- o Regulatory requirements
- o Quality Assurance Program requirements
- o Right of access to the supplier's plant facilities and records
- o Documentation requirements
- o Nonconformances and corrective actions
- o Spare and replacement parts

- o Commercial grade procurements
- o Standard Operating Procedures (SOPs)
- o EG&G Point-of-Contact (POC)

Once the requisition or contract is drafted, it shall be forwarded to the appropriate ER Division Manager for review and approval

4.3.1 Review and Approval of Procurement Document Packages

ER Department Division Managers or their designees shall assure that a review of procurement documents and necessary revisions are made. The review ensures that documents transmitted to subcontractors, contractors, or vendors include provisions that services and associated deliverables will meet specified requirements. The review also shall verify that procurement documents contain provisions for requiring contractors, subcontractors or vendors, and their subtiers, to implement appropriate QA programs. When required, written QA Programs are to be supplied prior to contract award.

After appropriate review, ER Department Division Managers shall approve or reject the procurement document package. Rejected procurement document packages shall be returned to the initiators. Approved procurement document packages shall be forwarded to the Quality Coordinators for the appropriate ER Divisions.

The applicable Quality Coordinator shall review the procurement document package to ensure it meets applicable regulatory requirements and the requirements of this QAPjP. After review, the QAO shall approve or reject the procurement document package. Rejected procurement document packages shall be returned to the appropriate ER Department Division Manager. Approved procurement document packages shall be forwarded to the EG&G Procurement Department.

Procurement Department personnel shall maintain the procurement document package and transcribe all applicable requirements and information into the final purchase order or contract. These final documents shall be prepared and processed in accordance with Procurement Department procedures.

Procurement Department personnel shall not make any changes to the technical or QA requirements without the written concurrence of the appropriate ER Department Division Manager(s) and the QAO prior to execution of the purchase order or contract.

Upon award of the purchase order or contract, Procurement Department personnel shall distribute copies to the appropriate EG&G Technical POC and the QAO.

4.3.2 Procurement Document Changes

Changes to procurement documents shall be subjected to the same review and approval process as required for the preparation of the original document.

4.3.3 Quality Assurance Records

Procurement Department personnel shall forward a legible copy of each QA Record, ER Department purchase request, contract, and applicable purchase order to the ER Department QA Records Management System in accordance with the requirements of Section 17 of this QAPjP.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 PURPOSE

This section establishes the requirements and methods by which Environmental Restoration (ER) Department instructions, procedures, and drawings are prepared, reviewed, and approved

5.2 APPLICABILITY

These requirements apply to all personnel involved in the generation, review, and approval of instructions, procedures, and drawings associated with the ER Program quality-affecting items or activities

5.3 REQUIREMENTS

5.3.1 Procedures

Approved instructions, procedures, and drawings for activities affecting quality will be followed as specified in this QAPjP and the specific WP/FSP/QAAs Standard Operating Procedures (SOPs) and Addenda to the SOPs (SOPAs) will be incorporated into the WP/FSP/QAA for approval. In the event that compliance is not feasible or appears to be unreasonable, the person making such a determination shall initiate action to resolve the questionable issue. In no event shall a documented requirement be bypassed or voided except by justified approval of the organization having authority for approving the requirement Such deviation to the procedure will be documented and approved utilizing the Procedure Deviation Notice (PDN) described in Section 5 3.8 Activities which typically fall into this category include the following

- o Field operations

- o Laboratory operations
- o Data assessment
- o Safety
- o Surveillances
- o Audits

Specific control requirements and related work instructions or procedures for these activities are described below

5 3 1 1 Field Operations Procedures

Field operations procedures are documented to ensure that field and sampling activities meet required technical and evidentiary standards for all phases of field activities. Field operations and sampling standard operations procedures (SOPs) will be approved specifically for ER Program use.

5 3 1 2 Laboratory Operations Procedures

In general, analytical procedures for ER samples must be consistent with the GRRASP and the specific WP/FSP/QAAS and established SOPs.

5.3.2 Procedure Development and Approval

SOPs shall be prepared for each activity to the level of detail required to ensure that the activity can be consistently performed as required. SOPs shall include or refer to appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been completed as specified and shall be uniquely identified, retrievable, and reproducible. If a SOP is canceled or superseded, its number will not be reused.

SOPs shall establish what is to be accomplished, by whom, when it will be done, under what conditions if conditions will affect quality, and where if location will affect quality. When procedures and instructions direct activities involving interfaces between organizations, they shall define those interfaces. They shall be sufficiently complete and detailed to ensure that data of known quality and integrity are generated to meet measurement objectives with a minimum loss of data due to out-of-control conditions. The SOPs shall be adequate to establish traceability of standards, instrumentation, samples, calibrations, and environmental data, consistent with sound scientific/engineering principles, consistent with current EPA regulations and guidelines, and consistent with the instrument manufacturer's specific instruction manuals if instrumentation is specified in the SOPs.

Procedures shall provide for documentation sufficiently complete to record the performance of all tasks and their results, explain the cause of missing information, and demonstrate the validation of information.

5.3.3 Procedure Format

Procedures shall be formatted to include the following sections as a minimum:

- o Unique procedure identifier, including revision number
- o Purpose statement: a short statement about why the procedure/instruction is written and what it contains
- o Applicability or scope: a short description of the organizations/positions and activities to which the requirements apply
- o Responsibilities: a description of specific positions/organizations identified within the procedure

- o Procedure a description of the actions necessary to accomplish the objectives identified in the purpose statement The description shall address samples, equipment, instruments, personnel qualifications, documentation, verification, software, calibration, data collection, storage, and reduction, records, and required materials, as appropriate
- o Approval signatures and effective date

5.3.4 Review

Procedures shall be reviewed for applicable technical, administrative, and quality requirement details This review shall be independent and performed by other than the original author

The reviews shall be performed by persons knowledgeable in the technical discipline and appropriate administrative details The Quality Assurance Officer (QAO) or designee shall review the procedure to assure incorporation of appropriate quality requirements

5.3.5 Approval

Procedures, instructions, specification drawings, specific personnel, applicable documents, authorities, and subsequent revisions or cancellations shall be approved by the appropriate Department, Director, and Division Managers and QAO The DOE, U S Environmental Protection Agency (EPA), and Colorado Department of Health (CDH) will also approve revisions and cancellations prior to use as specified in the IAG

5.3.6 Control and Issue

A written system for distribution and control of ER instructions, procedures, and drawings is identified in Section 6 of this QAPjP

5.3.7 Revisions

Changes to written instructions, procedures, or drawings for activities affecting quality shall be reviewed and approved in a comparable manner as the original documents by the same organization responsible for the original document

5.3.8 Change Control

A procedure deviation process includes the use of Figure 5-1, the Procedure Deviation Notice Instructions for the form's use are included on the form

5 3 8 1 Major Changes

Changes to documents, other than those defined as minor changes in section 5 3 8 2 below, are considered as major changes and shall be reviewed and approved by EPA, DOE, and/or CDH The reviewing organization(s) shall have access to pertinent background data or information upon which to base their approval

5 3 8 2 Minor Changes

Minor changes to documents, such as inconsequential editorial corrections or temporary changes that are issues not important to DOE, EPA, or CDH, shall not require that the revised documents receive their approval Instead, the original approvers shall sign the form shown in Figure 5-1 allowing the temporary change to take effect

5.3.9 Quality Assurance Records

A historical file of all original documents, and revisions and changes to instructions, procedures, and drawings shall be maintained in the QA Records Management System as described in Section 17 of this QAPjP

Figure 5-1

PROCEDURE DEVIATION NOTICE

Document I D _____ Yes No (See Section 2)

- Should this change be sent to DOE? Yes No
- Should this change be sent to EPA? Yes No
- Should this change be sent to CDH? Yes No

Action

If YES to any question, complete Section 1 and forward documents
If NO to all questions, complete Sections 1 and 2

Section 1 Current Description	
Recommended Change	
Initiator _____ Date _____ Manager _____ Date _____	
Section 2 Reasons for Temporary Change	
Change Expires on _____ (No longer than 6 months)	
Approved by Original EG&G Approval Personnel	Date
_____	_____
_____	_____
_____	_____
_____	_____

Figure 5-1 (Continued)
PROCEDURE DEVIATION NOTICE

**Instructions for Use of the
Procedure Deviation Notice**

- 1 Initiator of the form answers top three questions and follows the appropriate Action plan
- 2 Initiator completes Sections 1 and 2 as appropriate, and has his/her manager approve the form to this point The Manager's signature shows concurrence with all the information completed on the form upon his/her receipt
- 3 The form is then routed to the original approver(s) designees or replacements for signature Each signature attests to the accuracy of the information
- 4 When all the signatures are completed, the Temporary Change takes effect and lasts until the expiration date or six months from initiator signature, whichever is less

6.0 DOCUMENT CONTROL

6.1 PURPOSE

This section establishes the requirements and methods of control for the issue and distribution of QA documents

6.2 APPLICABILITY

This section applies to Environmental Restoration (ER) Program related procedures, SOPs, QAAs, QSSs, instructions, original data documents, decision documents, correspondence, and other designated documents, including changes

6.3 REQUIREMENTS

6.3.1 Document Issuance and Distribution

Following approval of documents as outlined in Section 5, documents will be released for issuance and distribution in accordance with written procedures. Control of documents involves issuing the correct revisions of the document to the designated individuals at the designated locations, and assuring that current documents are available prior to commencing work and at the location where work is to be performed. Document control practices include provisions for the following.

- o Identifying and marking documents, including documents released prior to completion of the approval process.
- o Maintaining controlled document distribution lists
- o Marking, removing, or destroying obsolete or superseded documents

- o Maintaining an index of revision status for controlled documents
- o Using receipt acknowledgement document transmittal forms, as applicable
- o Changing documents in a controlled manner

6.3.2 Quality Assurance Records

Documents generated as part of the Document Control process are to be made QA Records in accordance with Section 17 of this QAPjP

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 PURPOSE

This section establishes the requirements and methods for vendor selection and the control of purchased items and services

7.2 APPLICABILITY

These requirements apply to Environmental Restoration (ER) Department and ER Department-contracted personnel involved in the procurement of items and services for ER Program activities

7.3 REQUIREMENTS

7.3.1 Procurement Planning

Procurement planning is achieved through use of the checklist and documents specified in the "QA Plan for Procurement Requisitioners ER Program "

Procurement planning results in the documented identification of procurement methods and the sequence of actions, deliverables, and milestones Procurement planning also includes the tracking to the completion of these activities and the designation of applicable procedures for these activities

7.3.2 Acceptance of Items or Services

The method for acceptance of items or services will be identified on the checklists/forms provided in the "QA Plan for Procurement Requisitioners QA Program " Methods for accepting the final product shall be noted and may include

- o Receipt inspection through technical or peer review of the information
- o Receipt inspection through physical inspection of the product
- o Acceptance of Certificates of Conformance from the supplier
- o Post-installation testing of item, software, or other product
- o Surveillance or audit of activity
- o Technical verification of data produced
- o Review of objective evidence for conformance to the procurement document requirements (i e , certifications, reports, etc)

7.3.3 Selection of Contractors, Vendors, or Subcontractors

The selection of contractors, vendors, or subcontractors shall be based on evaluation of their ability to provide items or services in accordance with the requirements of the procurement documents prior to award of the contract or purchase order. The evaluation and selection shall be documented and shall include the contractor's/vendor's/subcontractor's history and capability of providing the service or product required.

7.3.4 Verification of Acceptability of Contractor/Supplier Performance

The extent of verification activities shall be a function of the relative importance, complexity, and quantity of the item or services procured. Verification activities shall be accomplished by the Quality Assurance Officer (QAO), or delegates.

7.3.5 Control of Contractor/Supplier Nonconformances

Contractors and suppliers will be required to submit any nonconformance or corrective actions generated in the development of their product or service. The QAO will coordinate the review of supplier nonconformances and corrective actions within the ER Department.

Methods used to accept an item or service from a supplier shall be a Supplier Certificate of Conformance substantiated by source verification, receiving inspection, post-installation test, or a combination thereof.

For procurement of services only, the service may be accepted by any or all of the following four methods:

- a Technical review of data produced,
- b Audit and(or) surveillance of the activity,
- c Review of objective evidence for conformance to the procurement document requirements, or
- d Supplier history. type, source, and quality rating

7.3.6 Quality Assurance Records

Records generated by the procurement process shall be maintained in accordance with Section 17 of this QAPjP.

8.0 IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA

8.1 PURPOSE

This section establishes the requirements and methods for identifying and controlling items, samples, and data that affect quality. These methods are used to assure that only correct and accepted items, samples, and data are collected, used, or installed.

8.2 APPLICABILITY

Identification shall be maintained for the items, samples, and data in traceable documents.

8.3 REQUIREMENTS

8.3.1 Items

8.3.1.1 Physical Identification of Items

Physical identification of items shall be used to the maximum extent possible. Identifying markings shall be permanent and legible and shall not adversely affect the function, service, or archival life of the item. When identification on the item is impractical, physical segregation, record traceability, or other methods shall be described in written procedures.

Items considered critical shall be physically identified by any of the following means, as applicable: (a) stenciled or etched markings, (b) strip markings, (c) imprinted tape, (d) tagging, (e) color coding, (f) records traceable to the item, (g) procedural control, or (h) other appropriate means in accordance with approved procedures.

When it is impractical to physically identify small items, these may be identified as to heat numbers, batch, lot, or specification by applying markings to bags, bins, tanks, or other suitable containers

Identification of items shall provide the required degree of traceability to pertinent documents. All markings shall be clear, unambiguous, indelible, and shall not affect the function of the item. Markings shall not be obliterated or hidden by surface treatment or coatings unless other means of identification is substituted. When an item is subdivided, markings shall be transferred to each part of the item.

If adhesive labels are selected as a method of item identification, the labels shall be evaluated for compatibility with the environment to which they will be exposed (e.g., radiation, temperature, weather, etc.) as well as the chemical composition of the adhesive on the labels in order to avoid contamination of the sample.

Only tags that can be attached to an item without damaging the item shall be used. The material that attaches the tag to the item must be evaluated to assure that it will not chemically alter the item.

Paints and other compounds used to mark items shall be evaluated to preclude affecting or damaging the items that are being identified and controlled.

8.3.1.2 Control of Items with Finite Shelf Life

Items with finite shelf life shall be controlled and physically identified to assure that they are provided the maximum protection for their shelf lives. Procedures shall identify the methods for dispositioning of items with expired shelf lives.

Storage areas shall be protected to provide for access control as well as maintenance of environmental storage conditions, (e.g., temperature, humidity, light, etc.) During storage,

provisions shall be made for maintenance or replacement of markings and identification records resulting from damage during handling or aging, for protection of identifications on items subject to excessive deterioration due to environmental exposure, and for updating existing records when the storage location changes

8.3.1.3 Distribution

When items with specific traceability requirements (i.e., personnel, date, organization, item, classification, transaction, return requirements, or documentation) are distributed outside of the Rocky Flats Plant (RFP), a distribution record will be completed to assure chain-of-custody (C-O-C) requirements are met. The transfer of the item shall be reflected in the quality assurance record.

8.3.2 Samples

8.3.2.1 General

A "sample" is physical evidence collected from a facility or the environment. An essential part of the QA Program is the control of this evidence (i.e., sample) gathered from the facility or environment. To accomplish this, sample identification and C-O-C procedures shall be followed. Samples required to be analyzed will be handled in accordance with the guidelines described in this section.

All samples shall have unique identification that traces the sample to the source(s) and indicates the method(s), date, and conditions prevailing at the time of sampling, as well as other pertinent information as described in the WP/FSP and SOPs.

The history of each sample and its handling is documented from its collection through all transfers of custody until it is transferred to an analytical laboratory. Internal laboratory records then document the custody of the sample through its final disposition.

8 3 2 2 Physical Identification of Samples

The method of identification of a sample depends on the type of measurement or analysis performed. When onsite measurements are made, the data shall be recorded directly in logbooks or field data records, with identifying information (including such information as project code, station number, station location, date, time, sampler), field observations, and remarks. Examples of onsite measurements include pH, temperature, conductivity, flow measurement, continuous air monitoring, and stack gas analysis. Sample identification requirements shall be outlined in the Work Plan/Field Sampling Plan/Quality Assurance Addendum (WP/FSP/QAA).

Samples shall be identified and controlled in a manner consistent with the intended use, and in compliance with EPA (CERCLA) Response Guidelines for RI/FS work. Samples shall be identified by placing the identification directly on the sample or container, or on records traceable to the samples. This unique number shall be contained in the sample collection logbook (as specified in WP/FSP/QAA) which identifies the sample.

If it is impractical to place complete identification on the sample, methods shall be described and documented in the WP/FSP/QAA to assure that samples are not mixed with like samples and that the correct identification of samples is verified and documented prior to release for use by a sample custodian. The unique sample identification (identifying sample origin and documentation) shall remain as the identification number from the point of sample collection through disposal.

8 3 2 3 Sample Labels

The sample labels shall be attached to each sample or container as specified in the Work Plan/Field Sampling Plan (WP/FSP) and Standard Operating Procedure (SOPs).

8 3 2 4 Chain-of-Custody

The purpose of these procedures is to preserve the representativeness and integrity of the samples during collection, transportation, and storage prior to analysis. A sample is considered to be in an individual's custody if the sample is: (1) in the physical possession of the responsible party, (2) in one's view after being in one's physical possession, (3) secured to prevent tampering, or (4) placed in a secured area by the custodian.

The C-O-C for sample flow from field collection to the receipt at the laboratory is illustrated in Figure 8-1. Sample identification and custody procedures, including C-O-C, shall be in conformance with authorized SOPs and the GRRASP (Exhibit III Section 1). EMAD must be contacted for destination laboratory identification and scheduling.

8 3 2 5 Sample Hold Times

Specific holding time references for samples are included in the GRRASP. Additional requirements may be identified in the site-specific WP/FSP/QAAs.

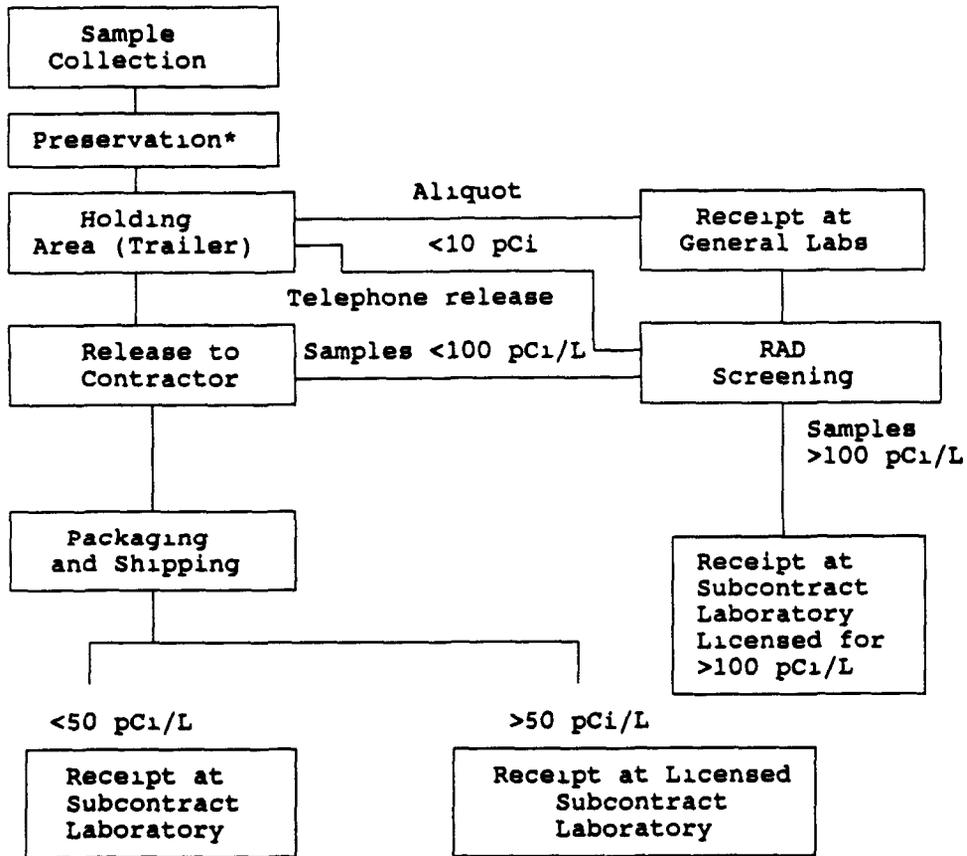
Sample Holding Times are defined as the duration between date of sample collection and dates of sample preparation (extraction/distillation) and analysis. For water samples, the holding times specified in 40 CFR 136 shall be applicable to this program. The Validated Time of Sample Receipt (VTSR) from the CLP-SOWs will also apply to laboratory holding times with one exception. The VOA holding time of 10 days is reduced to 7 days to conform with EPA data validation guidelines for volatile organics. Where discrepancies exist between the 40 CFR 136 criteria and CLP VTSR criteria, the former shall take precedence.

8 3 2 6 Sample Transport

Once samples are taken, they are transported from the sample location to a laboratory or other location for analysis. When sent by common carrier, samples, as required, shall be

packaged and labeled according to procedures specified by the U S Department of Transportation (DOT) (Code of Federal Regulations, 49) or the state, whichever is more stringent. However, before removal, a sample is often divided, depending upon the analyses to be performed. Each portion is preserved in accordance with approved SOPs and methods referenced in the WP/FSP/QAA. The sample container is identified by a sample label, the information recorded on the sample label plus amplifying remarks shall be present.

Figure 8-1
PROJECT CHAIN-OF-CUSTODY SAMPLE FLOW



Shipping containers shall be padlocked or sealed with custody tape to detect tampering for shipment to the laboratory. The method of shipment, courier name, and other pertinent information is entered in the "Remarks" section on the custody record. Sample shipments shall be accompanied by the C-O-C record identifying its contents. The original record shall accompany the shipment, and the copy shall be retained as specified in the SOP.

If samples are sent by mail, the package shall be registered with return receipt requested. If sent by common carrier or air freight, proper documentation must be maintained, e.g., bill of lading (which becomes an extension of the C-O-C).

When transferring the possession of samples, the individuals relinquishing and receiving shall sign, date, and note the time on the record. This record documents sample custody transfer from the sample, often through another person, to the sample custodian in the laboratory.

8.3.2.7 Sample Storage

While the samples are in storage (under C-O-C procedures), the proper environmental conditions shall be maintained to avoid degradation of the samples. Physical separation of samples to prevent mixing with like samples shall be accomplished to assure maximum traceability and safety of samples in storage.

8.3.3 Data

The identification of research data shall include reference to the origin of the data (i.e., organization of task, test, experiment, report, publication, etc.). Verification of the identification must be completed prior to release for use in order to assure traceability to the source(s).

A data storage and information system is the responsibility of the ER Department EMAD Division Manager. This system shall be capable of receiving all entered data; screening and

validating data to identify and reject outliers or errors, preparing, sorting, and entering all data into the data storage files (which are either computerized or manual) Data shall be stored in a manner that it will be traceable and retrievable It will be protected against damage, loss, or tampering

All data generated, produced, and archived shall be retrievable and traceable, as stated in the IAG These data are identified in the site-specific QAAs and Quality Summary Supplements (QSSs) The QAA shall specify the applicable QA Records to be maintained in accordance with Section 17 of this QAPjP

9.0 CONTROL OF PROCESSES

The methods for controlling processes within the Environmental Restoration (ER) Department which affect the quality of items and services or the validity of data are an integral part of other sections of this QAPjP, such as Section 3, Design Control, Section 4, Procurement Document Control, Section 8, Identification and Control of Items, Samples, and Data, Section 12, Control of Measuring and Test Equipment, and Section 13, Handling, Storage, and Shipping of Samples and Items

The activities associated with the ER program scientific investigations and feasibility studies do not include processes that need to be controlled in the sense of this criterion. Those activities requiring control are governed by technical procedures and other portions of this QAPjP

10.0 INSPECTION

10.1 PURPOSE

This section describes the requirements and methods for performing inspections of quality-affecting items or activities and the requirements for qualification and certification of inspection personnel

10.2 APPLICABILITY

These requirements are applicable to all Environmental Restoration (ER) Department Program personnel and their subcontractors who plan or conduct inspections of items, systems, or components (e g , inspection of monitoring wells, both materials and installation)

10.3 REQUIREMENTS

10.3.1 Personnel

- o Inspection personnel shall report to the QAO Inspection personnel shall not report directly to immediate supervisors who are responsible for performing the work being inspected
- o Personnel conducting inspections must be independent of the activity inspected
- o Inspection personnel who verify conformance of work activities for purposes of acceptance shall be qualified/certified to perform the assigned inspection task
- o Written procedures shall describe the methods and requirements for qualification and certification of inspection personnel

10.3.2 Inspection Planning

Inspection Planners shall consider the following

- o Identification of required procedures, drawings, and specifications, including revisions
- o Specification of necessary measuring and test equipment, including accuracy and precision requirements
- o Procedures for inspection hold points If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of ER Department representatives, these specific hold points shall be indicated in appropriate documents
- o Procedures for sampling The sampling procedure shall be based on approved sampling practices
- o Procedures for documentation Documentation shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of inspection results

10.3.3 Inspection Process

Inspections shall be performed using procedures, instructions, and/or checklists which provide the following as appropriate

- o Identification of activities and characteristics to be inspected.
- o The method of inspection

- o Requirements for the qualification of individuals responsible for performing the inspection operation
- o Acceptance and rejection criteria
- o Required procedures, drawings, and specifications
- o Specifications for measuring and test equipment required, including range and accuracy requirements
- o Documentation of what was inspected and when it was inspected

The inspection process relates the real-time inspection of activities and items to qualitative acceptance criteria defined in specifications, drawings, checklists, etc. A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process. Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction. When final inspections are performed, they shall include a records review of the results and resolution of nonconformances identified in prior inspections. The acceptance of items shall be documented and approved by authorized personnel.

10.3.4 Status Indicators

Status indicators (including calibration status labels, hold, accept, object, nonconforming material tags) shall be implemented as described in Section 14 of this QAPjP

10.3.5 Nonconformances

All nonconformances shall follow the procedures described in Section 15 of this QAPjP

10.3.6 Corrective Actions

Corrective actions shall follow the procedures described in Section 16 of this QAPjP

10.3.7 Quality Assurance Records

QA Inspection Records shall be handled in accordance with Section 17 of this QAPjP and, as a minimum, include the following

- o item/activity inspected
- o date of inspection
- o inspector signature
- o type of inspection - characteristics and objectives
- o inspection criteria employed
- o identification of the measuring and test equipment used during inspection
- o end results or acceptability
- o nonconformances and dispositions of nonconformances

11.0 TEST CONTROL

11.1 PURPOSE

This section describes the requirements and methods for test activities performed to demonstrate that the items and systems will perform satisfactorily

11.2 APPLICABILITY

This section applies to all Environmental Restoration (ER) Department and subcontractor personnel involved in test planning, approval, performance, documentation, evaluation, and disposition of final test results. Examples of tests include prototype qualification tests, bench scale and/or prototype waste treatability tests, production tests, proof tests prior to installation, pre-operational tests, and operational tests. The requirements of this section do not apply to scientific investigation activities. Equipment calibration is addressed in Section 12.

11.3 REQUIREMENTS

11.3.1 Test Requirements

Test requirements and acceptance or rejection criteria, including required levels of precision and accuracy, will be provided or approved by the responsible organization in the WP/FSPs/QAAs. Test requirements and acceptance or rejection criteria will be based on specified requirements contained in applicable design or other pertinent technical documents.

Tests necessary to validate quality attributes of an item shall be performed in accordance with approved, documented test procedures. These procedures shall provide the following information as applicable:

- o Test objectives
- o Test prerequisites, including such things as preparation and completeness of items to be tested, controlled environmental conditions, plant conditions, required system isolation and tagging requirements, and personnel training or qualifications
- o Range and accuracy requirements for calibrated measuring and test equipment, and need for special tools or materials
- o Acceptance/rejection criteria as defined in the applicable design and/or procurement documents
- o Safety precautions
- o Step by step testing instructions
- o Test monitoring requirements and mandatory inspection hold and witness points

11.3.2 Test Plans

Test plans shall include test objectives and make provisions for assuring that proper instrumentation is available and is used, necessary monitoring is performed, and suitable environmental conditions are maintained to avoid degradation of the test item. Test plans shall also address

- o Instrument calibration.
- o Training, qualification and certification requirements of test personnel
- o Type of measuring and test equipment required and their calibration requirements

- o Testing parameters and acceptance criteria
- o Environmental conditions
- o Potential sources of uncertainty and error

Test plans shall be reviewed and approved in accordance with the requirements in Section 5 of this QAPjP

11.3.3 Performance of Test Activities

ER Department and subcontractor personnel will conduct test activities in accordance with the requirements identified in test plans ER Department and subcontractor personnel will also assure that proper environmental conditions are maintained in the requisite activities and any deviations or nonconformances that may occur during these tests are documented and dispositioned in accordance with the requirements identified in Section 15 of this QAPjP

11.3.4 Test Results

Test results will be documented and their conformance with acceptance criteria evaluated by responsible and qualified personnel in order to assure that test requirements have been met

Test records will contain as a minimum

- o Item, system, or sample tested
- o Date of test
- o Unique identification of item and test equipment
- o Type of observation

- o Tester or data recorder identification
- o Tolerance requirements or acceptance criteria
- o Results and acceptability
- o Deviations and actions taken with regard to the deviations
- o Name of personnel evaluating results

11.3.5 Quality Assurance Records

These test results are considered as QA Records and will be maintained in accordance with the requirements in Section 17 of this QAPjP

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 PURPOSE

This section establishes the requirements and the methods for the control of measuring and test equipment (M&TE) used in ER Program activities. Specific test equipment will be identified in the QAAs for each workplan.

12.2 APPLICABILITY

The requirements are applicable to the ER Department and ER Department-subcontractors personnel whose activities involve the use of measuring and test equipment. Control of analytical laboratory equipment is addressed in the GRRASP. Other M&TE equipment will be identified in the WP/FSP/QAAs and applicable SOPs.

12.3 REQUIREMENTS

12.3.1 Selection

An all inclusive system is used for the calibration and maintenance of M&TE and measurement standards. The system provides for such items to be of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements. M&TE and measurement standards are calibrated and utilized in an environment controlled to the extent necessary to assure continued measurements of required accuracy, giving due consideration to temperature, humidity, vibration, cleanliness, and other controllable factors.

M&TE to be used for the determination of each major measurement parameter shall be selected such that the accuracy and precision of the M&TE meets or exceeds the accuracy and precision requirements for the parameter being measured. These requirements are

detailed in Section 3 of this QAPjP, which is intended to apply to all facets of M&TE use, calibration, maintenance, etc

12.3.2 Identification

M&TE is uniquely identified both on the specific item and in accompanying records. This is accomplished by physically marking the equipment with a unique identification number, status tag, color code, and/or calibration sticker that includes the M&TE unique identifier, calibration, and calibration due date. The identifier is recorded on the data sheet, log book page, etc, along with the data recorded when using that item.

12.3.3 Calibration

M&TE is calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid and traceable relationships to nationally recognized standards such as the National Institute for Standards and Technology (NIST) (formerly known as National Bureau of Standards). When nationally recognized standards exist, the basis for calibration is documented. Measurement standards used in the calibration system are supported by certificates, reports, or data sheets attesting to the description or identification of the item, the calibration source, date of calibration, calibration assigned value, statement of uncertainty, and environmental or other conditions under which the calibration results were obtained.

A Calibration Log is maintained for field instruments and all calibrations shall be documented in the log. Calibration stickers may be used to indicate calibration status. This log includes the following information as a minimum:

- o Unique identification of the M&TE (e.g., serial #12345)
- o Description of the item (e.g., Digital Multimeter, model #999X).

- o Frequency of Calibration (e g , every six months)
- o Date of last calibration
- o Date of next calibration
- o Traceability information (e g , Traceable to NIST voltage standard ser # 295123, Traceable to ASTM standard methodology for Sulfur Dioxide spike samples- ASTM-6543-1976)
- o Calibration Procedure (e g , SOP#CP-999Z-Rev 1, Fluke Multimeter Calibration Procedure for model 999X dated 7/4/90)
- o Preventative Maintenance Schedule (e g , any major preventative maintenance may be concurrent with calibration schedule)

12.3.4 Calibration Procedures

Written procedures are utilized for the calibration of all M&TE and measurement standards Calibration procedures specify the measurement standards and equipment to be used, the required parameter, range, and accuracy of the measurement standard, and the acceptable tolerance of each instrument characteristic being calibrated Each calibration procedure includes the following:

- o Reference to EPA-approved or other validated, standard methods
- o Specific acceptance criteria for all calibration measurements
- o Description of non-standard or modified methods and reference to specific SOPs to support these methods

- o Description of calibration frequency
- o List of critical spare parts

12.3.5 Preventative Maintenance Procedures and Schedules

M&TE and measurement standards shall be calibrated at periodic intervals to assure acceptable accuracy and reliability, where reliability is defined as the probability that the M&TE and measurement standard will remain in-tolerance throughout the established interval. A list of critical spare parts is included in the preventative maintenance procedures.

A tracking system is utilized to provide for a calibration schedule of M&TE and measurement standards to assure timely recalibrations, thereby precluding use of an instrument beyond its calibration due date. Prior to use of M&TE, personnel verify that the calibration due date has not expired. If the calibration due date has expired, the item shall be tagged and segregated if possible, and a Nonconformance Report prepared in accordance with Section 15 of this QAPjP.

12.3.6 Nonconformance

If any M&TE or measurement standard is found to be significantly out-of-tolerance during the calibration process, the calibration system shall provide for the notification to the respective user and the Quality Assurance Officer (QAO) of the out-of-tolerance condition with associated measurement data so that appropriate action can be taken.

12.3.7 Handling and Storage

Proper protection, storage, handling, and environmental conditions is maintained for M&TE. The effects of environmental or other factors on an item's uncertainty is considered when calibration specifications are established and appropriate protection measure taken. Limitations on the handling, use, and storage of items is defined in the applicable calibration test, and item-specific M&TE implementing procedures.

12.3.8 Commercial Devices

Calibration and control measures are not required, for example, with rulers, tape measures, levels, and other such devices, when normal commercial equipment provides adequate accuracy.

12.3.9 Quality Assurance Records

Documents generated as a result of control, use, or calibration of M&TE are considered to be QA Records, and are maintained in accordance with the requirements of Section 17 of this QAPjP. Records documenting the schedules and procedures to maintain the accuracy of M&TE and measurement standards include individual calibration records or other means of control for each item. Such records shall provide a description or identification of the item, calibration interval, date calibrated, identification of the calibration source, calibration procedure used, calibration results, and calibration actions taken. In addition, the individual record of any item whose accuracy must be reported via a calibration certificate or report shall state the certificate or report number.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 PURPOSE

This section establishes the requirements and methods for the handling, storage, and shipping of items. Specific requirements for handling samples and chain-of-custody (C-O-C) are discussed in Sections 3 and 8 of this QAPjP. The methods discussed in this section ensure that the items which affect quality are controlled to prevent damage or loss and to minimize their deterioration. The handling, storage, and shipping of hazardous wastes are addressed in Rocky Flats Plant (RFP) Resource Conservation and Recovery Act (RCRA) Hazardous and Mixed Waste Standard Operating Procedures (SOPs).

13.2 APPLICABILITY

These requirements apply to all Environmental Restoration (ER) Program activities in which personnel handle, store, package, ship, or receive items which if damaged, lost, or deteriorated, could affect quality.

13.3 REQUIREMENTS

13.3.1 Procedures

When required for critical, sensitive, perishable, or high-value articles, procedures (SOPs) or instructions for handling, shipping, storage, packaging, and preservation shall be referenced or prepared (as noted in Section 8.3.2.6, Sample Transport, or in Section 8.3.2.7, Sample Storage). These procedures shall include at a minimum:

- o Identifying the item or category of items to be controlled by the procedure

- o Referencing any applicable codes or standards
- o Indicating the degree of cleanliness, preservation, and packaging required
- o Specifying the step-by-step sequence of operations to be followed in handling, shipping, and storing the item or class of items
- o Specifying the level of experience and training required to perform the handling, storage, and shipping activities required
- o Specifying special handling tools and equipment required (e g , cranes, lifts, slings)
- o Specifying special identification or marking requirements, and the verification of these markings (markings and labeling will be established to adequately identify, maintain, and preserve the item, and specify any special controls needed)
- o Specifying maximum storage and retention times (shelf life, holding time), including necessary disposal requirements
- o Specifying unique equipment requirements (e g , containers, preservatives, temperature, etc)
- o Specifying QA audit and surveillance requirements

13.3.2 **Additional Requirements**

Shipping documentation should accurately reflect tag and serial numbers for tagged items

When applicable, traceability shall be maintained at all times for the items to be shipped, from the point of origination to the final receipt of the item or material

Packaging requirements shall be specified for protection against corrosion, contamination, physical damage, or any effect which would affect the item or cause deterioration during handling, storage, or shipping

13.3.3 Quality Assurance Records

Documents generated as a result of handling, storage, and shipping of items are considered to be QA Records, subject to the requirements identified in Section 17 of this QAPjP

14.0 STATUS OF INSPECTION, TEST, AND OPERATIONS

14.1 PURPOSE

This section identifies the requirements and methods for use of physical status indicators or supporting documentation for item and system inspection, test (treatability, aquifer tests, etc), and operation

14.2 APPLICABILITY

These requirements are applicable to personnel involved in controlling the status of items or systems, and to personnel involved in using material, operating systems, or entering areas with status indicators

14.3 REQUIREMENTS

14.3.1 Status Identification

The status of inspection and test activities will be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. The status of nonconforming, inoperative, or malfunctioning systems and components will be documented and identified to prevent inadvertent use.

Status will be maintained through indicators, such as physical location and tags, markings, stamps, inspection records, or other suitable means. Physical status indicators and status documentation will address:

- o The operating status of the system or component
- o Activities which require the use of these indicators
- o Proper unique identification to provide for traceability
- o Out-of-service conditions

The use of these indicators shall not adversely affect the characteristics or function of the item. Examples of physical status indicators include "Do Not Operate," "Hold," "Accept," "Reject," and "Nonconforming Material."

14.3.2 Quality Assurance Records

Documents generated as a result of controlling test and operating status are considered QA Records and shall be controlled as specified in Section 17 of this QAPjP.

15.0 CONTROL OF NONCONFORMANCES

15.1 PURPOSE

This section defines the requirements, and methods for identifying, controlling, evaluating, and dispositioning nonconformances in items, services, samples, and data

15.2 APPLICABILITY

These requirements are applicable to all personnel who discover, evaluate, and/or provide dispositions to nonconformances. Nonconformances in analytical laboratories are addressed in the EG&G General Radiochemistry and Routine Analytical Services Protocol (GRRASP) and are described in Section 3 of this QAPjP

15.3 REQUIREMENTS

15.3.1 Definition of Nonconformance

A nonconformance consists of a deficiency in the characteristics, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. For ER purposes, reference to nonconforming "conditions" or "items" includes activity, item, service, data, material, equipment, structure, or condition

15.3.2 Identification of Nonconformances

Upon discovering a nonconformance, the initiator shall prepare a Nonconformance Report (NCR) (see Figure 15-1). The NCR shall identify the requirements that were violated, the actual nonconforming condition, and any immediate actions needed or taken to correct the condition. The NCR shall be forwarded to the Quality Assurance Officer (QAO) for further disposition

Figure 15-1
 NONCONFORMANCE REPORT

	NCR No. _____	DATE _____
	QAL _____	PAGE _____ OF _____
	AUTH # _____	BLDG # _____
	PROJ NCR No _____	P O # _____

PROJECT _____
 RESPONSIBLE DEPARTMENT _____
 ITEM _____ QUANTITY _____
 SPECIFICATION REFERENCE _____
 NONCONFORMANCE DESCRIPTION _____

ISSUED BY _____ DATE _____
 Title _____ Organization _____
 MANAGER CONST MGMT & INSPECTION _____ DATE _____

PRELIMINARY DISTRIBUTION

<input type="checkbox"/> BLDG MGR	<input type="checkbox"/> MANAGER FE	<input type="checkbox"/> PROJ ENGR	<input type="checkbox"/> CM&I MASTER FILE	<input type="checkbox"/> SEISMIC QUAL
<input type="checkbox"/> HS&E AREA ENGR	<input type="checkbox"/> CONSTRUCTION COORDINATOR	<input type="checkbox"/> CONTRACTOR	<input type="checkbox"/> PURCHASING	<input type="checkbox"/> FIRE PROT ENGR
			<input type="checkbox"/> OTHER	

DISPOSITION

<input type="checkbox"/> USE AS-IS	<input type="checkbox"/> REPAIR	<input type="checkbox"/> REWORK	<input type="checkbox"/> REJECT	<input type="checkbox"/> AS-BUILT REQUIRED
------------------------------------	---------------------------------	---------------------------------	---------------------------------	--

DISPOSITION APPROVALS

PROJECT ENGR _____ DATE _____ DESIGN CHECKER _____ DATE _____
 HS&E AREA ENGR _____ DATE _____ USER _____ DATE _____
 PURCHASING (IF APPL.) _____ DATE _____ FIRE PROT ENGR _____ DATE _____
 SEISMIC QUAL _____ DATE _____ FQA _____ DATE _____

INTERIM DISTR

<input type="checkbox"/> MANAGER MTCE	<input type="checkbox"/> PURCHASING	<input type="checkbox"/> PROJ ADMIN.	<input type="checkbox"/> OTHER
<input type="checkbox"/> CONSTR COORD	<input type="checkbox"/> CM&I MASTER FILE	<input type="checkbox"/> CONTRACTOR	<input type="checkbox"/> APPROVERS

15.3.3 Segregation of Nonconforming Items, Services, Samples, and Data

Nonconforming items, samples, and data shall be segregated, when practical, by placing them in a clearly identified and designated hold area until the related NCR has been resolved. When segregation is impossible or impractical due to physical conditions, environmental conditions, size, weight, access limitations, or other such reasons, other precautions shall be taken to preclude inadvertent use of a nonconforming item, service, sample, or data. These precautions may include tagging, flagging, securing, or posting security measures. Associated records, documents, or containers shall indicate the NCR number to advise others that a nonconformance has been detected. Upon closure of the NCR, the segregation or precautionary measures are no longer required and shall be removed by the QAO or designee.

15.3.4 Disposition of Nonconformances

The QAO shall assign the NCR to the responsible Division Manager(s), or shall provide the disposition for nonconformances limited to QA activities. Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming conditions shall be proposed and approved by the responsible Division Manager and the QAO. The disposition shall include a statement of the cause of the condition, the recommended action required to correct the nonconformance, and other applicable measures to prevent recurrence of the condition.

Based upon the actions described in the NCR, the dispositions for nonconforming items shall be categorized as one of, or a combination of, the following:

- o Use-As-Is Use of an item, service, sample, or data will not result in an adverse condition and will continue to meet all functional requirements, including performance, maintainability, fitness for use, and safety. Technical justification for this deviation from the original requirements shall be provided in the NCR. The

documents and/or records associated with the nonconformance will reflect the NCR to provide traceability to the identification and resolution of the condition

- o Rework Actions taken will restore the item, service, sample or data to meet the original specified requirements Reworked items are required to be retested and/or verified using the original acceptance criteria
- o Repair Actions taken will correct the item, service, sample, or data to meet acceptable requirements, even though it did not conform with the original specified requirements Technical justification for this deviation from the original requirements shall be provided in the NCR The documents and/or records associated with the nonconformance shall reflect the NCR number to provide traceability to the identification and resolution of the condition
- o Reject No actions can be taken to correct or restore the item, service, sample, or data to meet requirements. The item, service, sample, or data must be scrapped or returned to the contractor/supplier

15.3.5 Approvals

The appropriate Division Manager, or delegate, shall review and approve dispositions to NCRs resolved within their Division. The QAO, or delegate, also shall review and concur with the NCR disposition.

15.3.6 Tracking, Verification, and Closure

The QAO or delegate shall track and monitor the status of open NCRs until closure The QAO, or delegate, shall verify the implementation and effectiveness of disposition actions prior to closure of the NCR Verifications shall be conducted by personnel independent of the condition and actions being verified Upon verification of implementation of the actions

and the generation of the required records, the QAO shall close the NCR and notify the responsible Division Manager(s).

15.3.7 Determination of Root Cause

In order to assure effective corrective action, the root cause of the problem identified in NCRs shall be identified, documented, and analyzed as part of the trend analysis system described in Section 16 of this QAPjP

15.3.8 Quality Assurance Records

Documentation related to the generation, disposition, evaluation, justification, and closure of NCRs are QA Records that shall be maintained in accordance with the requirements of Section 17 of this QAPjP The records, tags, flags, etc used as precautionary measures to prevent inadvertent use are not QA Records and do not need to be maintained beyond the use described in this section

16.0 CORRECTIVE ACTION

16.1 PURPOSE

This section describes the requirements and methods for identifying, documenting, and verifying corrective actions originating from conditions considered to be adverse to quality

16.2 APPLICABILITY

These requirements are applicable to personnel involved in identifying corrective actions resulting from audits, surveillances, assessments, investigations, nonconformance reports (NCRs), unplanned events, or other activities

16.3 REQUIREMENTS

16.3.1 Identification of Conditions Adverse to Quality

Conditions adverse to quality are conditions where established operating limits, specifications, standards, or administrative control systems have not been implemented effectively and the results could have a significant impact on Environmental Restoration (ER) Program activities. Upon identification of a condition adverse to quality, the initiator shall prepare a Corrective Action Report (CAR) (see Figure 16-1). The CAR shall be forwarded to the Quality Assurance Officer (QAO) for disposition.

16.3.2 Responding to CARs

The QAO shall assign the CAR to the responsible Division Managers or Department Director for response, or the QAO shall provide a response for CARs limited to QA activities.

Figure 16-1
 ER PROJECT CORRECTIVE ACTION REPORT

ER PROJECT CORRECTIVE ACTION REPORT			
AR No. ERP _____		AUDIT/SURVEILLANCE No. _____	
SEVERITY LEVEL _____		Page _____ of _____	
ORIGINATION	1. Location Reference	3. Responsible Organization	4. Identified by (Originator)
	5. Previous Findings		6. Response Due Date
	During Audit/Surveillance/Other	During Audit Exit Meeting	
	7. Requirement		
	8. Deficiency		
RESPONSE	9. Discussion and Recommended Action(s)		
	10a. ATL/STL Date	10b. QA Manager/Date	
	11a. Cause		
	11b. Remedial/Investigative Action(s)	11c. Implementation Date _____	
	11d. Action(s) to Prevent Recurrence	11e. Scheduled Implementation Date _____	
	12. Name Title	Signature	Date
	13. RESPONSE	ATL/STL/Date	QA Manager/Date
	__Accept__Amend__Reject		
	14. AMENDED RESPONSE	ATL/STL/Date	QA Manager/Date
	__Accept__Reject		
EVALUATION	15a. VERIFICATION	15b. REMARKS	
	__Satisfactory__Unsatisfactory		
	REP. AUDIT/SURVEILLANCE NO.	ATL/STL/Date	QA Manager/Date
	16. DATE OF CAR CLOSURE		

SAMPLE FORM

Response actions should be commensurate with the type, importance, complexity, priority, and health and safety of the public and ER Department personnel. CAR responses shall provide the following, as applicable:

- o Investigative action(s) to determine the scope or extent of the condition
- o Root cause(s) of the problem(s)
- o Action(s) to correct the specific problem(s)
- o Action(s) taken for similar or related conditions
- o Action(s) taken to preclude recurrence of the root cause(s)
- o Schedule for completion of action(s)

16.3.3 Evaluation and Closure of CARs

The QAO, or delegate, shall evaluate responses to CARs to assure that the requirements and specific deficiencies have been addressed. Upon approval of the proposed response and completion of scheduled action(s), the QAO shall verify the implementation and effectiveness of the corrective action(s). For audit findings, the QAO shall assure that the lead auditor/team leader is involved in the evaluation of the response and verification of the action(s).

Following satisfactory verification of implementation, the QAO shall close the CAR and notify the responsible Division Manager(s) or Department Director(s). Unsatisfactory verifications shall result in the issuance of a new or revised CAR to describe the adverse condition.

The QAO shall track and monitor the status of open CARs to assure timely resolution and closure

16.3.4 Trend Analysis

The QAO shall establish a trend analysis program that identifies the overall trends of the ER Program. The program shall include analysis of CARs and NCRs, analysis of open and closure rates, and root cause analysis, and shall identify positive and negative trends. Trend analysis reports shall be issued periodically, to the ER Department Director, with additional distribution to appropriate Division Managers

16.3.5 Quality Assurance Records

Documentation associated with generation, evaluation, closure, and analysis of CARs and Trend Analysis Reports are QA Records that shall be maintained in accordance with Section 17 of this QAPJP

17.0 QUALITY ASSURANCE RECORDS

17.1 PURPOSE

This section establishes the requirements and methods for the generation, control, validation, maintenance, and disposition of QA Records which are a result of Environmental Restoration (ER) Program activities

17.2 APPLICABILITY

These requirements are applicable to activities which generate, process, or verify documents and records supporting quality-affecting activities and site investigations QA Records are completed documents that furnish evidence of the quality of items and/or activities affecting quality Documents are any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures or results

17.3 REQUIREMENTS

17.3.1 Records System

The records management system shall collect, maintain, and protect QA Records to provide evidence of ER Program compliance with governing requirements Specific locations for the storage and maintenance of QA Records shall be developed and staffed by records management personnel.

Records shall be accepted by records management personnel when they are identified as QA Records Records and/or indexing systems(s) shall provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which it applies Documents which are clearly marked as "Preliminary Draft" (working draft prior to review

and approval) or "Information Copy" (uncontrolled copy) shall not be routinely maintained by the records management personnel

The Quality Assurance Addenda (QAA) shall specify the applicable QA Records to be maintained in accordance with this Section. QA Records include, but are not limited to, the following

- o Records prepared and maintained to demonstrate implementation of QA programs (e g , audit and surveillance plans, reports, and corrective actions)
- o Specific correspondence and directives
- o Plans and procedures
- o Data, maps, photographs, logs, field notebooks, data sheets, lab analysis
- o Drawings, designs
- o Other materials that provide data and record quality
- o Documents that relate in any way to the presence of Rocky Flats Plant (RFP) hazardous substances, pollutants, or contaminants
- o Documents that relate in any way to the implementation of the Interagency Agreement (IAG)

17.3.2 Generation of Records

QA Records resulting from implementation of this QAPjP, standard operating procedures (SOPs), and other project documents shall be submitted to records management personnel for handling. This transfer of QA Records shall be conducted annually, as a minimum.

17.3.3 Record Authentication

Documents shall be considered valid records only if stamped, initialed, or signed and dated, or otherwise authenticated. Authentication may take the form of a statement by the responsible individual or organization. Documents are authenticated to assure that those records designated as official QA Records have been validated to be legible, complete, and of microfilmable quality. Authentication may occur at the time of issuance of the record or prior to transmittal to records management personnel. Records may be originals or quality acceptable reproduced copies. Permanent ink shall be used on all documents which are to become QA Records.

17.3.4 Record Index and Classification

Records management personnel shall generate a records index which identifies the record type to be produced on the project, the unique identifier, the record retention time, and the location of the record within the record system. Records management personnel and/or ER Department supervision shall classify records as to their retention status (i.e., lifetime/permanent records, nonpermanent records, and records with limited storage and retention requirements).

17.3.5 Record Revisions or Corrections

Management shall decide and list those persons authorized to change or correct information on documents that have been designated as QA Records. The methods to be used (by authorized persons only) for correcting QA Records are as follows:

- o Corrections to QA Records Corrections shall be made by scribing a single black line through the incorrect information and entering the correct information in close proximity to the lineout. The correction shall include the date and initials of the person who made the correction.
- o Regeneration of QA Records The record management personnel or person generating a record shall inform the Quality Assurance Officer (QAO) that a QA Record has been lost or damaged beyond repair. The QAO shall provide guidance as to the method for regeneration or replacement of the record. (See ANSI/ASME NQA-1-1989, Supplement 17S-1 for guidance.)

17.3.6 Records Receipt, Storage, Preservation, and Safekeeping

A system shall be identified for receipt control of records by the records management personnel for permanent and temporary storage. This system shall include:

- o A method for designating the required records
- o A method for identifying the records received
- o Procedures for receipt, inspection, and acceptance of incoming records.
- o A method for submittal of completed records to the storage facility(ies) without undue delay

Records shall be stored in a manner that protects them against damage from moisture, temperature, pressure, larceny, rodents, sunlight, and other environmental considerations until submitted to the record storage facility(ies) The record storage facility(ies) shall be constructed in a manner which minimizes the risk of damage or destruction See ANSI/ASME NQA-1-1989, Supplement 17S-1 for facility storage options Single or dual storage may be utilized, as long as measures are taken to provide for replacement, restoration, or substitution of lost or damaged records. A list shall be maintained designating those personnel who shall have direct access to the QA Record files in the record storage facility(ies)

17.3.7 Retention of Records and Documents (Interagency Agreement Part 38)

Documents and records that relate in any way to the presence of hazardous substances, pollutants, or contaminants at the RFP, or to the implementation of the IAG, shall be preserved for a minimum of 10 years after termination of the IAG This includes all documents identified as being in the possession of the U S Department of Energy (DOE) or its divisions, employees, agents, accountants, or contractors No document retention policy less stringent than this policy may supersede this policy. After the ten-year period, DOE shall notify the U S Environmental Protection Agency (EPA) and the State of Colorado at least 45 days prior to destruction or disposal of any such documents or records EPA and the State of Colorado will make a determination if the documents should be retained for a longer period of time

18.0 QUALITY VERIFICATIONS

18.1 PURPOSE

This section establishes the requirements and methods for conducting quality verifications to determine the adequacy and effectiveness of an operation, task, process, or activity

18.2 APPLICABILITY

These requirements are applicable to personnel performing verification activities, including audits, surveillances, assessments, reviews, and other methods of evaluating quality activities. They do not apply to inspections. Personnel selected for verifications shall be independent of the activities being evaluated.

18.3 REQUIREMENTS

18.3.1 Audits

The Quality Assurance Officer (QAO), or delegate, shall develop a comprehensive audit schedule to provide coverage of Environmental Restoration (ER) Program activities commensurate with the importance and complexity of the activities.

18.3.1.1 Personnel Selection and Training

Auditors shall have training and experience commensurate with the scope and complexity of the activities to be evaluated and shall have training, qualifications and certification (per ANSI/ASME NQA-1-1989) for conducting audits. Personnel identified as lead auditors or audit team leaders shall be certified to perform these activities. The QAO shall provide specific requirements and methods for training, qualifying, and certifying audit personnel.

18 3 1 2 Audit Preparation

The QAO shall assure that the selected auditors complete the necessary preparation activities including

- o Notice of Audit The appropriate organization, manager, or director shall be notified prior to commencement of the audit. This shall be accomplished by written notice EG&G retains the right to conduct unscheduled and unannounced audits
- o Development of Audit Plans The plans shall identify the audit scope, applicable governing requirements and documents, activities to be audited, personnel or organization(s) to be notified, and a tentative schedule
- o Development of Audit Checklists The checklists include the specific requirements to be verified and for documenting the results of the verification
- o Instruction of Personnel The lead auditor/team leader shall assure that audit personnel have completed appropriate instruction and are familiar with the requirements for the audit

18.3.1 3 Audit Reporting and Corrective Actions

Audit reports shall include the following as a minimum

- o Description of the audit scope
- o Identification of the auditors
- o Identification of personnel contacted during the audit activities

- o Summary of audit results, including a list of deficiencies and a statement on the effectiveness of the quality assurance program elements that were audited.
- o Suggestive corrective action(s), where applicable, and recommendations for improvement where possible
- o Description of each reported or nonconforming condition in sufficient detail to identify the applicable NCRs or CARs generated in accordance with Sections 15 or 16 of this QAPJP. Conditions requiring prompt corrective action shall be reported immediately to Division Managers, Department Directors, or organization officers, as appropriate

18 3 1 4 Performance and System Audits and Frequency

Field operations and laboratory analysis activities related to ER Department conduct of Resource Conservation and Recovery Act Facility Investigation/Corrective Measures (RFI/CMS) investigations are subject to system and performance audits to ensure that field and laboratory procedural mechanisms are operative, conform to project requirements, and are effectively implemented in compliance with the Interagency Agreement (IAG) and U S Department of Energy (DOE) orders. A system audit consists of evaluation of all components of the measurement system to determine their proper selection and use, as well as an in-depth review of programmatic compliance, implementation, and effectiveness of the QA program. A performance audit consists of evaluating the implementation and effectiveness of a particular procedure, item, task, or operation

The type and frequency of system and performance audits shall be established by the QAO and submitted to the ER Department Director. Written audit reports shall be submitted to.

- o EG&G Rocky Flats ER Department Director
- o Appropriate Division Managers

- o QAO
- o Others as appropriate

18 3 1 5 Field Operations Audits and Frequency

At least one independent (external) performance audit shall be conducted during

- o Activities to describe the nature and extent of contamination (IAG Section VI B 3)
- o Activities to evaluate site characteristics (IAG Section VI B 4)

At least annually, internal system audits shall be conducted regarding Data Management Procedures in accordance with IAG Section VI B 5. At a minimum, information gathered during each characterization shall be audited for consistency and adequacy of record by examination of field logs for accordance with methods described in the WP/FSP/QAA. Field logs will be audited for use in documenting observations, measurements, and significant events that occurred during field activities. Additional audits of field activities may be scheduled at the discretion of the ER Department Director, Division Managers, or the QAO. Surveillance may be utilized as a performance audit to verify that corrective action has been taken and effectively implemented. Written reports shall be prepared for external and internal audits and surveillances of field activities.

18 3 1 6 Laboratory Audits and Frequency

At least one independent system audit shall be performed by EG&G, or delegate, on an annual basis for each laboratory analyzing ER Program samples. Laboratory reports used to describe the nature and extent of contamination, and to evaluate site characteristics, shall document sample custody, analytical responsibility, analytical results, adherence to prescribed protocols, nonconformity event, corrective measures, and/or data deficiencies. Field reports, sample shipment records, and analytical results shall be audited to ensure that they maintain

sample management and tracking so that only validated analytical data are reported and utilized in the development and evaluation of corrective/remedial alternatives

Written reports shall be prepared for laboratory audits conducted in accordance with the following procedures

- o EG&G Rocky Flats, Procedures for Conducting Organic Laboratory Audits
- o EG&G Rocky Flats, Procedures for Conducting Inorganic Laboratory Audits
- o EG&G Rocky Flats, Procedures for Conducting Radiochemistry Laboratory Audits

In addition, in compliance with the IAG, annual performance audits shall be conducted to ensure that

- o Laboratories used for analyses participate in a QA Program equivalent to that of, and approved by, the EPA, as required in Part 33, Section 195 E of the IAG
- o Analyses of data collected for each site's characterization meet the DQOs developed in the WP/FSP/QAA (or revised during the RFI/CMS) as required in Section VI.B.4 of the IAG.

Audits are considered closed upon satisfactory correction of deficiencies identified by the audit. Verification of audit closing shall be confirmed by the QAO. Notification of audit closure shall be prepared by the team leader or lead auditor, confirmed by the QAO, and issued to the appropriate organization, Division Manager, or Department Director

18.3.2 Surveillances

The QAO, or delegate, shall develop a surveillance schedule to provide coverage of ongoing ER Program activities. Surveillances are intended to supplement audit verifications. Many instances occur where real-time observations of ER Program activities are required. Schedules are not required for surveillances performed under strict time constraints.

18.3.2.1 Personnel Selection and Training

Designated surveillance personnel shall have training and experience commensurate with the scope and complexity of the activities to be evaluated. The QAO shall provide specific requirements and methods for training, qualifying, and, if deemed appropriate, certifying surveillance personnel.

18.3.2.2 Surveillance Preparation

The QAO shall assure that the selected surveillance personnel complete the necessary preparation activities including

- o Notice of Surveillance. The appropriate organization, manager, or director shall be notified prior to or at commencement of the surveillance. This can be accomplished by telephone notice or by letter/memorandum providing written notice.
- o Development of Surveillance Plans. The plans may identify the surveillance, scope, applicable governing requirements and documents, activities to be verified, personnel or organizations to be notified, and a tentative schedule.
- o Development of Surveillance Checklists. The checklists may include the specific requirements to be verified and may provide for documenting the results of the

verification Checklists are not required for surveillances If used, they should meet audit guidelines

- o Instruction of Personnel The QAO or audit team leader shall assure that surveillance personnel have completed appropriate instruction and are familiar with the requirements of the surveillance.

18 3 2 3 Reporting and Corrective Actions

Surveillance reports shall be written in a format that provides the most appropriate information to the target audience Executive summaries shall be provided to the maximum extent practical and as appropriate to the situation The reports shall include the following, as a minimum:

- o Description of surveillance scope
- o Identification of surveillance personnel
- o Identification of personnel contacted during the surveillance
- o Summary of results, including a statement of effectiveness of the activities that were evaluated.
- o Description of each reported adverse or nonconforming condition in sufficient detail to identify the applicable NCRs or CARs generated in accordance with Sections 15 or 16 of this QAPjP. Conditions requiring prompt corrective action(s) shall be reported immediately to the responsible director, manager, or organization officer

Surveillances are considered closed upon correction of deficiencies identified by the surveillances. Notification of surveillance closure shall be prepared by the designated surveillance personnel or team leader, confirmed by the QAO, and issued to the appropriate organization officer, Division Manager, or Department Director.

18.3.3 Reviews

Reviews to assure quality may include peer reviews, technical reviews, or design reviews. Reviews are conducted as required by applicable requirements governing the preparation and issue of documents, or as directed by the QAO, Department Director, or Division Manager(s).

18.3.3.1 Selection of Reviewers

Reviewers shall be selected based upon acknowledged qualifications and expertise in the subject matter to be verified. When deemed appropriate, reviewers shall receive instruction in preparing, conducting, and documenting reviews.

18.3.3.2 Reporting and Resolution of Review Comments

Prior to initiating the review, review criteria shall be identified. The review results shall be recorded on the document being evaluated or written on records accompanying the document being evaluated.

Review comments shall be categorized to indicate technical or editorial significance, and proposed resolution. The comments will be returned to the organization, Division, or Department responsible for the document being evaluated for action to accept or reject the comments. Disputed comments shall be resolved by the appropriate Division Manager, the QAO, or the ER Department Director.

18.3.4 Management Assessments

The overall adequacy and effectiveness of the ER QA Program shall be determined by conducting assessments of each Division or the ER Department on an annual basis. Contracted or internal organizations performing management assessments shall be required to provide assessment reports to the appropriate Division Manager(s), the ER Department Director, and the QAO.

The management assessments shall consider the following

- o Effectiveness of controls that achieve and assure quality
- o Adequacy of resources and personnel provided to the QA Program
- o Adequacy of personnel training

The most common methods of performing management assessments are:

- o Review of management reports (status reports, technical reports, etc.).
- o Review of quality verification reports (audit reports, surveillance reports, inspection reports, test reports, etc.).
- o Review of corrective action reports including trend analysis reports on a regular basis.
- o Interviews.

18.3.5 Quality Assurance Records

Documentation related to quality verification activities, as described in this section, are QA Records that shall be maintained in accordance with the requirements of Section 17 of this QAPjP

19.0 SOFTWARE QUALITY ASSURANCE

19.1 PURPOSE

This section defines the the requirements and methods for the control and documentation of computer software utilized for Environmental Restoration (ER) Program activities

19.2 APPLICABILITY

This section applies to computer software used by the ER Department or subcontractors to produce or manipulate data, particularly data which is reported to state or federal regulatory agencies Specific details for the implementation of the requirements contained in this section are contained in ER Department software control procedures The extent to which these requirements apply is related to the nature, complexity, and importance of the software application

19.3 REQUIREMENTS

Computer software will be developed, controlled, and maintained to reduce the likelihood of defects entering executable codes during development, modification, and operation, and to ensure that the end product satisfies the requirements of its intended application. Software will be verified, validated, and documented consistent with the nature, complexity, and its intended application

19.3.1 Software Development

Software development shall be accomplished in a traceable, planned, and orderly manner The number of phases and relative emphasis placed on each phase of software development will depend on the nature and complexity of the software. Software development may be performed in an iterative or sequential manner

19 3 1 1 Requirements

During this phase, the requirements that the software must satisfy that pertain to functionality, performance, design constraints, attributes, and external interfaces shall be specified, documented, and reviewed. These requirements shall define the response of the software to input data, and shall provide the detail and information necessary to design the software. The requirements shall be approved by the appropriate level of management as described in written procedures.

19 3 1 2 Design

During this phase, a software design based on the requirements shall be developed, documented, reviewed, and approved. The design shall specify the overall structure (control and data flow), and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures).

19 3 1 3 Implementation

During this phase, the design shall be translated into a programming language, and the implemented software shall be analyzed to identify and correct errors. Implementation phase software verification activities shall consist of the examination of source code listings to assure adherence to internal coding standards and conventions.

19 3 1 4 Testing

During this phase, the design as implemented in code shall be exercised by executing the test cases. Failure to successfully execute the test cases shall be reviewed to determine if modifications of the requirements, design, implementation, or test plans and test cases are required. The code shall not be used until the cause is found.

Testing phase activities shall consist of the validation of the code to assure adherence to the requirements, and to assure that the software produces correct results for the test cases. To evaluate technical adequacy, the software test case results can be compared to results from alternative methods, such as

- o Analysis without computer assistance
- o Other validated computer programs.
- o Experiments and tests
- o Standard problems with known solutions
- o Confirmed published data and correlations

19 3 1 5 Installation and Checkout

During this phase, the software becomes part of a system incorporating applicable software components, hardware, and data. The process of integrating the software with applicable components may consist of installing hardware, installing the program, and verifying that all components have been included. Installation and checkout phase software verification and validation activities shall consist of

- (a) The execution of tests for installation and integration, and
- (b) The documentation of the approval of the software for operational use

19.3.2 Commercial Software

Where commercial "off-the-shelf" software is used, including codes available in the public domain, it shall be placed under the configuration controls required by this section prior to use. Available documentation from the software supplier shall be obtained in order to evaluate the software's adequacy. Examples of this type of software include mathematical/numerical data reduction software, models, data management software, computer language compilers, etc. Source code is generally not available and controls are limited to unique version identification and user-related manuals for such software. Documented validation is required to demonstrate that the software performs its stated capabilities and functions.

19.3.3 Acquired Software

"Acquired Software" is non-commercial software acquired from organizations outside the ER Department. Software which has not been developed or originated by the ER Department, and is not commercially available, requires documented validation to demonstrate that the software performs its stated capabilities and functions. ER Department or subcontractor personnel shall test the software in accordance with written test plans to validate the software. The specific form of the test plan is up to the tester but must identify the software options to be tested, the data to be used as input, the expected results, and the acceptance criteria.

19.3.4 Software Verification and Validation

Software verification and validation activities shall:

- (a) ensure that the software adequately and correctly performs all intended functions,
and

- (b) ensure that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system

Software verification and validation activities shall be planned and performed for each system configuration which may impact the software. The results of software verification and validation activities shall be documented. Software verification and validation shall be performed by individuals other than those who designed the software.

19 3 4 1 Software Verification

Software verification shall be performed during the software development to ensure that the products of a given cycle phase fulfill the requirements of the previous phase or phases.

19 3 4 2 Software Validation

Software validation is performed at the end of the implementation phase to ensure that the code satisfies the requirements. Software validation activities, such as the development of test plans and test cases, shall be integrated into each phase of the software life cycle. Testing shall be the primary method of software validation. The validation of modifications shall be subject to selective regression testing to detect errors introduced during the modification of systems or system components, to verify that the modifications have not caused unintended adverse effects, or to verify that a modified system(s) or system component(s) still meets specified requirements.

Testing shall be the primary method of software validation. The validation of modifications shall be subject to selective regression testing to detect errors introduced during the modification of systems or system components, to verify that the modifications have not caused unintended adverse effects, or to verify that a modified system(s) or system components(s) still meets specified requirements.

19.3.5 Software Configuration Control

19 3 5 1 Configuration Identification

A configuration baseline shall be defined at the completion of the software development. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recent approved software configuration.

19 3 5 2 Configuration Change Control

Changes to software shall be formally documented. This documentation shall contain a description of the change, the rationale for the change, and the identification of affected baselines. The change shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to software baselines.

19.3.6 Software Documentation

Software documentation will be maintained as a QA record as discussed in Section 17 of this QAPjP. Such documentation will include

- o software requirements
- o software design documentation
- o software change documentation.
- o description of mathematical models and numerical methods.

- o software validation documentation
- o software configuration management documentation
- o user's instructions or manual

19.3.7 Software Application Control

Application control, the control of how an application is run, shall be implemented for software runs performed to generate or process data to develop conclusions that are to be reported to regulatory agencies, and to document testing done for software validation purposes. The requirements for software application control will be contained in written procedures which will be developed by the end function responsible for performing the analysis prior to the application's use.

19.3.8 Software Security

Access to computer software and computer-based data shall be controlled to prevent possible accidental or malicious misuse, modification, or disclosure.

19.3.9 Software Deficiencies

Deficiencies in software shall be documented on the Nonconformance Report (NCR) and dispositioned in accordance with Section 15 of this QAPjP. Software users shall be notified of deficiencies found in software so they may determine any impact on previously reported results or conclusions.

19.3.10 Quality Assurance Records

The documentation requirements identified in this section and referenced ER Department software control procedures constitute QA Records and shall be maintained in accordance with the requirements identified in Section 17 of this QAPjP.

The Quality Assurance Addenda (QAA) shall specify the applicable QA Records to be maintained in accordance with the requirements identified in Section 17 of this QAPjP

APPENDIX A
DATA QUALITY OBJECTIVE DEVELOPMENT PROCESS

Data quality objectives (DQOs) are developed through a three-stage process, as shown in Figure A1 1. Although the three stages are discussed sequentially in the following subsections, they should be performed in an interactive and iterative manner. The DQO process is integrated with development of the Sampling and Analysis Plan included in the specific work plan and should be revised based on the results of each data collection activity. Figure A1 2 illustrates integration of the three-stage DQO process into the planning for a phased Remedial Investigations/Feasibility Studies (RI/FS), as an example.

STAGE 1 - IDENTIFY DECISION TYPES

The major elements of Stage 1 include

- o Identifying and involving data users
- o Evaluating available data
- o Developing a conceptual model
- o Specifying objectives and decisions

Figure A1 3 shows the Stage 1 elements

DATA USERS

The data users for Rocky Flats Environmental Restoration (ER) activities consist of decision-makers, program management staff, and technical personnel. These users are described below.

Decision Makers

The principal decision-makers are identified as the federal officials responsible for Rocky Flats Plant (RFP) operations and the federal and state regulatory officials responsible for environmental protection.

U S Department of Energy (DOE) - Office of Environmental Restoration and Waste Management

The DOE is identified as the owner of the RFP and the lead federal agency responsible for operation of the facility. The DOE-Office of Environmental Restoration and Waste Management is charged with coordinating ER Programs conducted at DOE facilities under its jurisdictions. The identified decision-makers are the Secretary of Energy and the Acting Assistant Secretary for Environmental Restoration and Waste Management.

Figure A1.1
DQO DEVELOPMENT STAGES

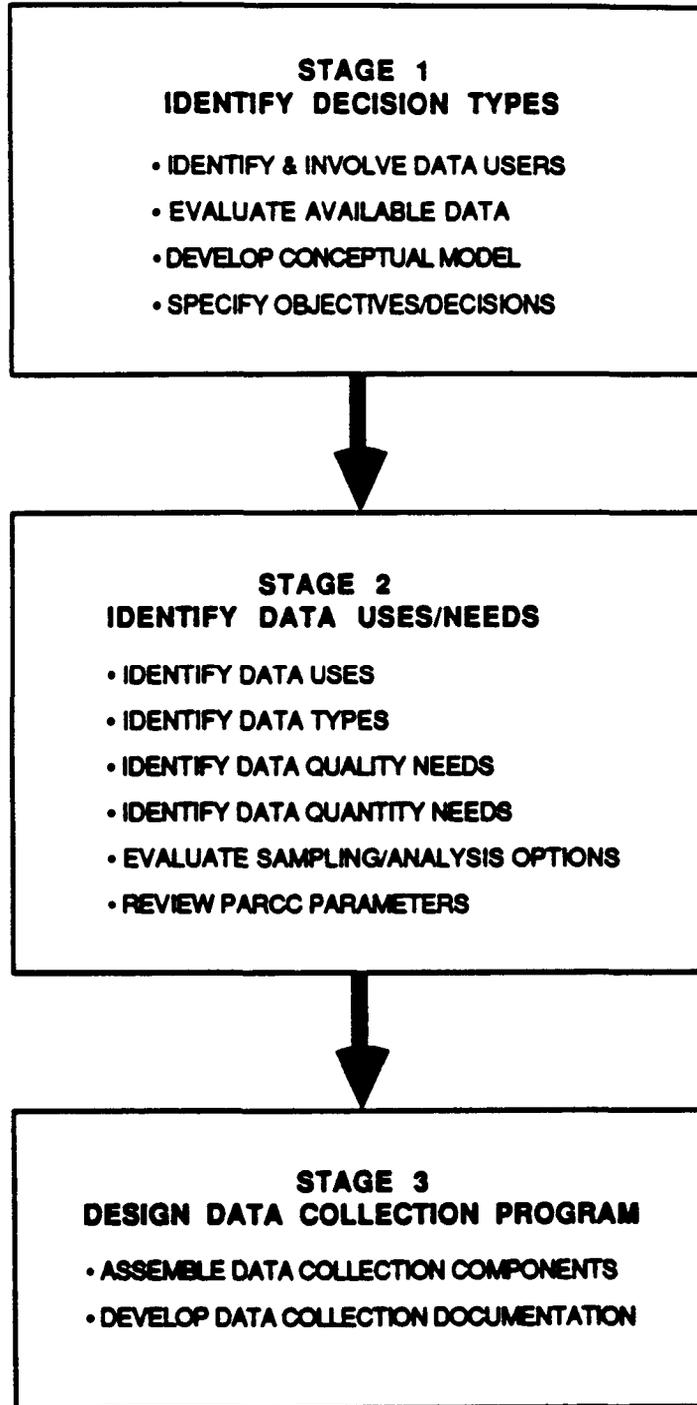


Figure A1.2
 DQO PROGRESS WITHIN PHASED WORK
 FLOW FOR EXAMPLE RI/FS

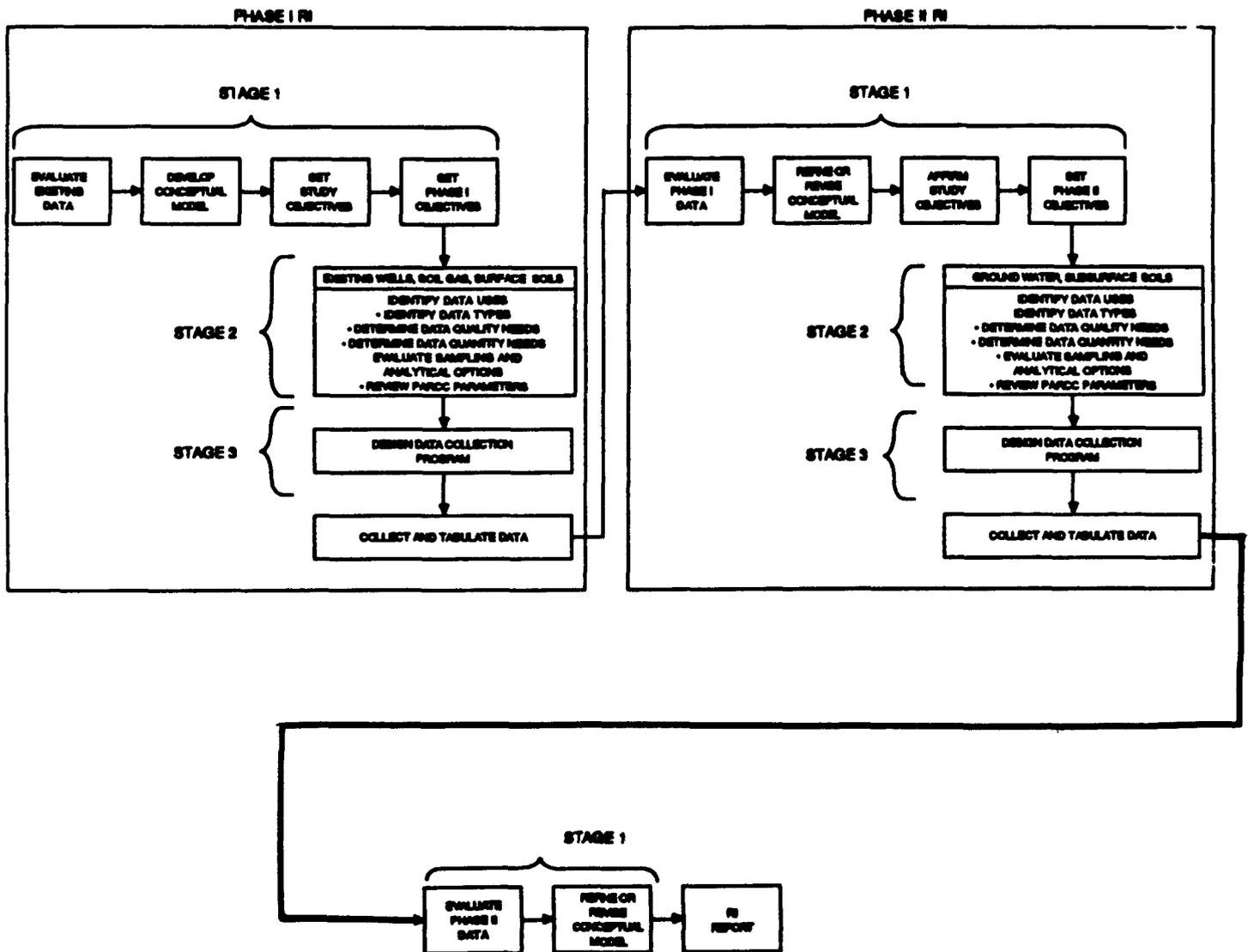
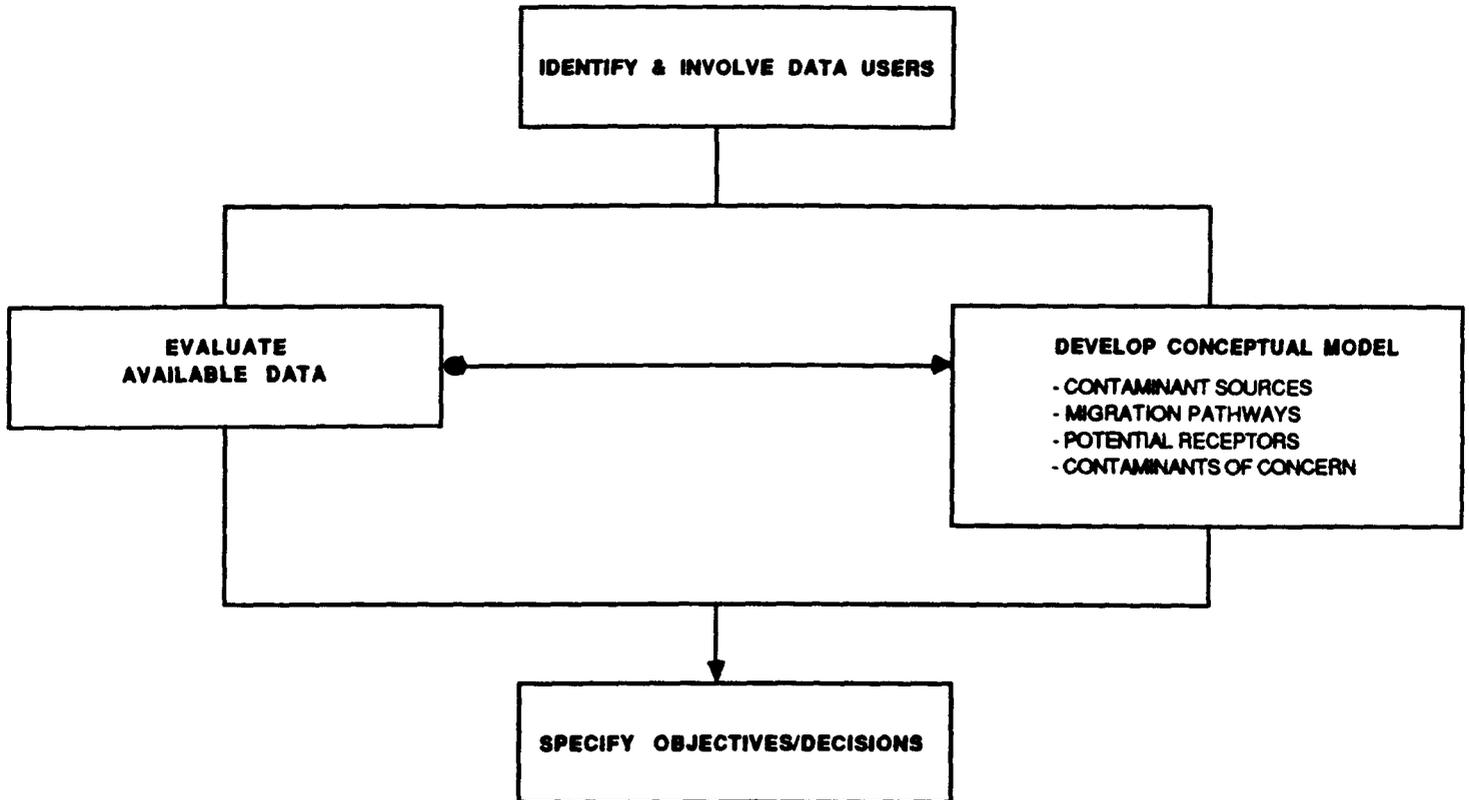


Figure A1.3
STAGE 1 ELEMENTS



U S Department of Energy - Rocky Flats Office (RFO)

The DOE/RFO group charged with supervising the ER Program at the RFP is Environmental Management. The identified decision-makers are the DOE/RFO Deputy Manager and the Acting Environmental Restoration Branch Chief.

U S Environmental Protection Agency (EPA) Region VIII

The EPA-Region VIII group overseeing environmental restoration activities at the RFP is the Waste Management Division. The identified decision-makers are the Waste Management Division Director, Rocky Flats Remedial Project Manager (RPM), and Resource Conservation and Recovery Act (RCRA) and Comprehensive Environmental Restoration and Compensation Liability Act (CERCLA) Branch Chiefs.

State of Colorado Department of Health (CDH)

The CDH group overseeing the ER Program at the RFP is the Hazardous Materials and Waste Management (HMWM) Division. The identified decision-makers are the HMWM Division Director, the Hazardous Waste Section Leader, and the Unit Leaders of the Hazardous Waste Facilities Unit and the Monitoring and Enforcement Unit.

Program Management Staff

The principal program management staff are identified as the prime EG&G contractor personnel responsible for ER Program activities.

EG&G Rocky Flats Plant Environmental Restoration (ER) Department

The EG&G Rocky Flats, Inc. ER Department has primary responsibility for planning and implementation of ER projects at RFP. The identified data users are the Associate General Manager for Environmental Restoration and Waste Management, the ER Department Director, ER Department Division Managers, and matrix project personnel from other RFP or external EG&G organizations.

Technical Personnel

The principal technical personnel are identified as the EG&G RFP Technical Specialists and subcontractors responsible for supervising, coordinating, and performing ER activities.

EVALUATION OF EXISTING DATA

Available information will be reviewed and evaluated as the initial step in the RI/FS and/or RFI/FS process. A number of factors relate to the quality of data and its adequacy for use, including the following considerations:

- o Age of the data.
- o Analytical methods used
- o Detection limits of the methods
- o QA/QC procedures and documentation

The evaluation will be summarized in the specific work plan and should be as thorough and accurate as possible.

DEVELOPMENT OF CONCEPTUAL MODEL

Conceptual models describe a site and its environs and present hypotheses regarding the contaminants present, their routes of migration, and their potential impact on sensitive receptors. Figure A1.4 shows the basic elements of a conceptual model for an uncontrolled hazardous waste site.

SPECIFY OBJECTIVES/DECISIONS

In a broad sense, the objective of a remedial action program is to determine the nature and extent of the release or threat of release of hazardous substances and to select a cost effective remedial action to minimize or eliminate that threat. The primary purpose for collecting environmental measurement data specified in this QAPjP is to support investigations of the Solid Waste Management Units (SWMUs) contained in each of the Operable Units (OUs) on the RFP, as identified in the Rocky Flats Plant/Interagency Agreement (RFP/IAG). The specific objectives of the project and the decisions that must be made must be discussed in the specific WP/FSP and summarized in the QAA. Table A1.1 lists general RI/FS objectives.

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FIGURE A1.4
ELEMENTS OF A CONCEPTUAL MODEL

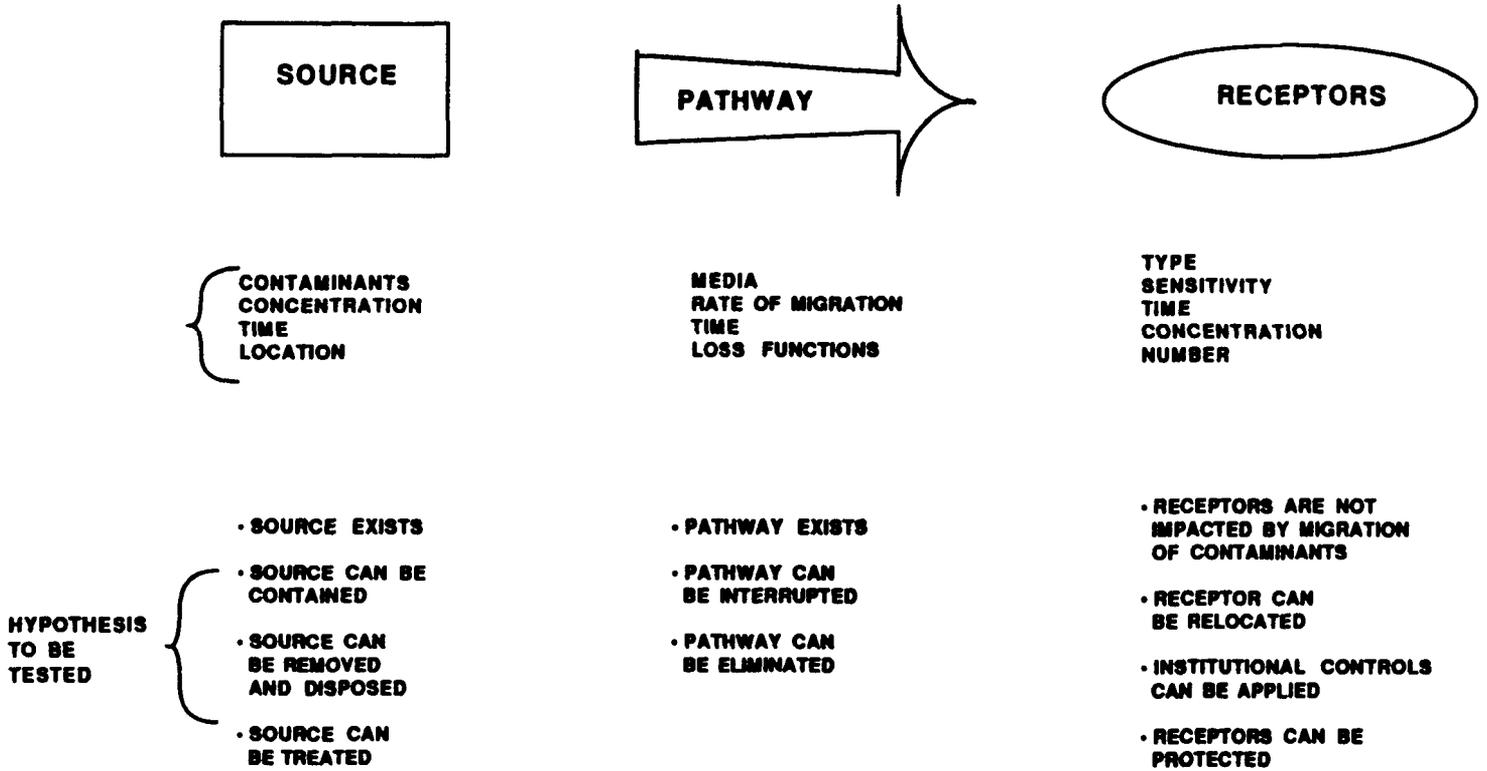


Table A1.1
GENERAL RI/FS OBJECTIVES

Objective	RI Activity	FS Activity
- Determine presence or absence of contaminants	- Establish presence/absence of contaminants at source and in all pathways.	- Evaluate applicability of no action alternative for source areas/pathways.
- Determine types of contaminants	- Establish "nature" of contaminants at source and in pathways, relate contaminants to PRP-cost recovery	- Evaluate environmental/public health threat, identify applicable remedial technologies
- Determine quantities (concentrations) of contaminants	- Establish concentration gradients	- Evaluate costs to achieve applicable or relevant and appropriate standards
- Determine mechanism of contaminant release to pathways	- Establish mechanics of source/pathway(s) interface	- Evaluate effectiveness of containment technologies
- Determine direction of pathway(s) transport	- Establish pathway(s)/transport route(s), identify potential receptor(s)	- Identify most effective points in pathway to control transport of contaminants
- Determine boundaries of source(s) and pathways	- Establish horizontal/vertical boundaries of source(s) and pathway(s) of contamination	- Evaluate costs to achieve relevant/applicable standards, identify applicable remedial technologies
- Determine environmental/public health factors	- Establish routes of exposure, and environmental and public health threat	- Evaluate applicable standards or risk, identify applicable remedial technologies
- Determine source/pathway contaminant characteristics with respect to mitigation (bench studies)	- Establish range of contaminants/concentrations	- Evaluate treatment schemes

STAGE 2 - IDENTIFY DATA USES/NEEDS

Stage 2 of the DQO development process identifies data uses and specifies the types of data needed to meet the project objectives. Although data needs are identified generally during Stage 1, Stage 2 specifically defines data uses.

The major elements of Stage 2, as shown in Figure A1 5, are

- o Identify data uses
- o Identify data types
- o Identify data quality needs
- o Identify data quantity needs
- o Evaluate sampling/analysis options
- o Review PARCC parameters

Stage 2 begins after the conceptual model is developed and overall project objectives are established.

IDENTIFY DATA USES

Data uses must be stated very specifically to serve their purpose in development of DQOs. The most common data use categories are:

- o Site Characterization (geologic, air, surface water, groundwater, etc)
- o Health and Safety
- o Risk Assessment
- o Environmental Evaluation
- o Evaluation of Alternatives

Table A1 2 is a form that may be used to document the thought processes involved in determining what the data will be used for. The form may be included in the specific work plan.

IDENTIFY DATA TYPES

Data use categories define the general purposes for which data will be collected. Based on the intended uses, a concise statement regarding the data types needed can be developed.

The data collected from RFP field activities will be used in conjunction with existing data to determine availability and toxicity of the contaminants of concern to the environment on the RFP. Data types will consist of field survey data and laboratory analytical results of samples.

Figure A1.5
DQO STAGE 2 ELEMENTS

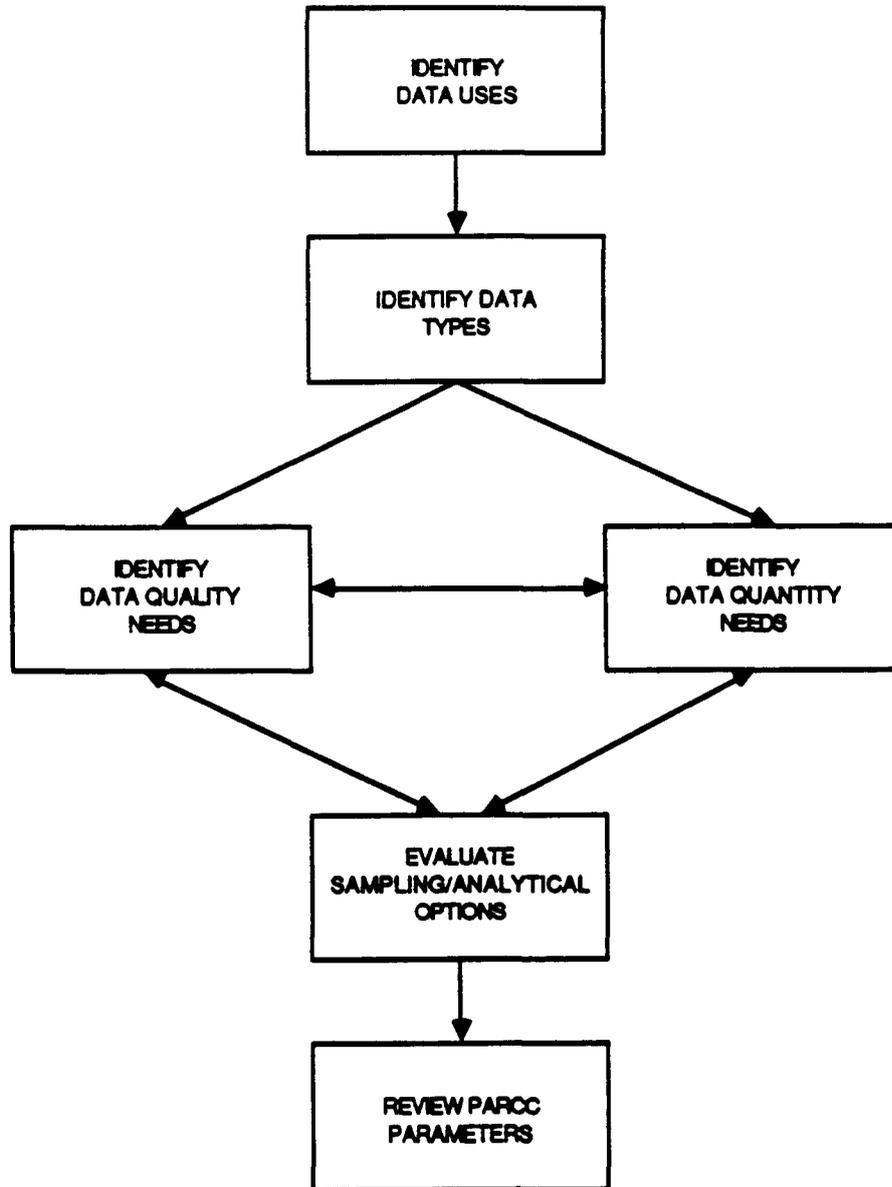


Table A1.2
 DATA USES

SITE
 NAME _____
 LOCATION _____
 NUMBER _____
 PHASE _____
 R11 R12 R13 ERA FS RD RA

EPA REGION _____

DATE _____
 CONTRACTOR _____
 SITE MANAGER _____

DATA USE MEDIA	SITE CHARACTERIZATION (INCLUDING HEALTH & SAFETY)	RISK ASSESSMENT	EVALUATION OF ALTERNATIVES	ENVIRONMENTAL EVALUATION	OTHER
SOURCE SAMPLING TYPE _____					
SOIL SAMPLING					
GROUND WATER SAMPLING					
SURFACE WATER SEDIMENT SAMPLING					
AIR SAMPLING					
BIOLOGICAL SAMPLING					
OTHER _____					

NOTE. CHECK APPROPRIATE BOX (ES)

CDM SF D00 1.001

Typical media that will be sampled and/or surveyed during ER activities are

- o Terrestrial Media
 - Vegetation
 - Invertebrates
 - Vertebrates

- o Aquatic Media
 - Vegetation
 - Invertebrates
 - Vertebrates

- o Physical Media
 - Surface water
 - Groundwater and vadose zone moisture
 - Sediments/sludges
 - Surface soils and subsurface materials
 - Air

The sampling and survey data will be used to determine the extent of potential contamination, the nature of the contamination, and the potential exposure pathways

Specific field survey and laboratory analysis data needs for each of the media types are described below:

FIELD DATA

Terrestrial Media

Sampling and survey methods for terrestrial media are currently under development and will be described in the WP/FSP/QAA for "Environmental Evaluation" (EE) activities. The EE WP/FSP/QAA and the subcontractor-specific QSSs will contain the specific field survey and laboratory analysis data requirements for each media type.

Aquatic Media

Sampling and survey methods for aquatic media are also required for the EE and are currently under development. The WP/FSP/QAA for EE will describe in detail the sampling and survey data requirements for the aquatic media types

Physical Media

- o Hydrogeologic Data Hydrogeologic data, including groundwater, vadose zone moisture and subsurface materials information, are needed primarily for determining geologic and hydrologic characteristics of the RFP site and specific site areas under investigation. This information will also be used in contaminant pathway analysis.

Geologic data are obtained from geologic mapping, drilling, and geophysical logging activities. Hydrologic data are obtained from hydrologic mapping, well installation, well completion, and surface water measurement activities. Data collected during these activities are recorded in logging formats prescribed in subcontractor technical specification documents and according to project WP/FSP/QAA.

Air, surface soils, and sediments sampling and survey methods are required for site characterization and pathway analysis. Details are specified in the WP/FSP/QAAs.

Laboratory Analysis Data

- o Organic Chemistry Organic chemistry data includes the compounds on EPA's Contract Laboratory Program (CLP) Target Compounds List (TCL) and as specified in the EG&G General Radiochemistry and Routine Analytical Services Protocol (GRRASP) as well as other compounds identified in the DQO process. Analyses for organics are essential because some of these compounds have been identified in groundwater, surface water, and soil samples collected during Phase I Remedial Investigation studies. These analyses are needed for comparison of CERCLA sites and RCRA closure units data with Applicable or Relevant and Appropriate Requirements (ARARs).
- o Inorganic (Metals) Chemistry Soil, sediments, groundwater, surface water and tap water include analytes listed in the CLP Inorganic Target Analyte List (TAL) and for any additional parameters specified in the GRRASP or in the DQO process.
- o Other Water Quality Parameters Analyses needed for other water quality parameters include, but are not limited to, the following
 - Bicarbonate
 - Carbonate/Bicarbonate
 - Chloride
 - Nitrate
 - Nitrite as N
 - Sulfate
 - Sulfide
 - Total Dissolved Solids
 - Total Suspended Solids
 - Dissolved Oxygen
 - Oil and Grease
 - Phosphate
 - % Solids
 - % Moisture
 - pH
 - Specific Conductance
 - Temperature
 - Alkalinity

- o Radiochemistry. Radiochemistry analyses are needed for soil, sediments, groundwater, and surface and tap water samples. The following radionuclide analyses will be performed
 - Plutonium^{239, 240}
 - Americium²⁴¹
 - Uranium^{233, 234}
 - Uranium²³⁸
 - Uranium²³⁵
 - Tritium
 - Strontium^{89,90}
 - Cesium¹³⁷
 - Gross Alpha
 - Gross Beta
 - Radium²²⁶
 - Radium²²⁸
 - Curium²⁴⁴
 - Neptunium²³⁷
 - Thorium^{230,232}

These analyses are needed for comparison with EPA and CDH ARARs and RFP background data. In some cases, the RFP background concentrations are lower than ARAR values. Methods available for conducting most of these analyses are included in the GRRASP.

- o Air Quality. Radioactive ambient air data are required for air monitoring samples. Radiochemistry analyses are needed for radioactive ambient air samples.

These analyses provide data for compliance under the Clean Air Act (CAA) and address the ARARs. Methods employed for analysis are not available under CLP, and have been developed in SOPs for the ambient air analyses. A radioactive ambient air monitoring program procedure is utilized to provide control of this activity.

IDENTIFY DATA QUALITY NEEDS

Consideration of data quality needs should begin with the identification of data uses and data types. Important factors in defining data quality include.

- o Prioritized data uses
- o Appropriate analytical levels
- o Contaminants of concern.
- o Levels of concern.
- o Required detection limit
- o Critical samples

Analytical Levels

Table A1 3 summarizes analytical levels appropriate to data uses. Table A1 4 is a form that should be used to document the analytical levels chosen for each type of data use. The form should be included in the WP/FSP.

IDENTIFYING DATA QUANTITY NEEDS

The number of samples which should be collected can be determined using a variety of approaches. The validity of the approach is dependent on the characteristics of the media under investigation and the assumptions used to select sample locations. A statistician may be utilized in determining the necessary quantity of data.

EVALUATE SAMPLING/ANALYSIS OPTIONS

Following the identification of data uses, data types, and data quality and quantity needs, an evaluation of sampling and analysis options can be undertaken. Numerous sampling and analysis options could be developed for any data collection activity. The possible options are based on the data types needed.

The options chosen for sampling and analysis must be specifically described in the WP/FSP and summarized in the QAA.

Table A1 5 is a form for summarizing the DQO information and decisions made up to this point. It should be completed and included in the specific WP/FSP and the information summarized in the QAA.

REVIEW PARCC PARAMETER INFORMATION

The PARCC parameters consist of precision, accuracy, representativeness, comparability, and completeness. The parameters are indicators of data quality. Ideally, the end use of the measurement data should define the necessary PARCC parameters. In the ideal situation, numerical precision, accuracy, and completeness goals would be established and these goals used in selecting the measurement methods. However, RI/FS work doesn't typically fit this ideal scenario. RI/FS sites are so different that it is impractical to set universal PARCC goals at the outset. Instead, historical precision and accuracy achieved by different standard analytical methods should be reviewed as an aid in selecting the most appropriate technique.

The specific objectives associated with each of these parameters are dependent on the intended use(s) of the data. Specific objectives are described in WP/FSP/QAA prior to initiating any sampling or analysis activities.

Table A1.3
 SUMMARY OF ANALYTICAL LEVELS APPROPRIATE TO DATA USES

DATA USES	ANALYTICAL LEVEL	TYPE OF ANALYSIS	LIMITATIONS	DATA QUALITY
SITE CHARACTERIZATION MONITORING DURING IMPLEMENTATION	LEVEL I	TOTAL ORGANIC/INORGANIC VAPOR DETECTION USING PORTABLE INSTRUMENTS FIELD TEST KITS	INSTRUMENTS RESPOND TO NATURALLY-OCCURRING COMPOUNDS	IF INSTRUMENTS CALIBRATED AND DATA INTERPRETED CORRECTLY CAN PROVIDE INDICATION OF CONTAMINATION
SITE CHARACTERIZATION EVALUATION OF ALTERNATIVES ENGINEERING DESIGN MONITORING DURING IMPLEMENTATION	LEVEL II	VARIETY OF ORGANICS BY GC, INORGANICS BY AA, XRF TENTATIVE ID- ANALYTE SPECIFIC DETECTION LIMITS VARY FROM LOW ppm TO LOW ppb	TENTATIVE ID TECHNIQUE/INSTRUMENTS LIMITED MOSTLY TO VOLATILES, METALS	DEPENDENT ON QA/QC STEPS EMPLOYED DATA TYPICALLY REPORTED IN CONCENTRATION RANGES
RISK ASSESSMENT PRP DETERMINATION SITE CHARACTERIZATION EVALUATION OF ALTERNATIVES ENGINEERING DESIGN MONITORING DURING IMPLEMENTATION	LEVEL III	ORGANICS/INORGANICS USING EPA PROCEDURES OTHER THAN CLP CAN BE ANALYTE-SPECIFIC RCRA CHARACTERISTIC TESTS	TENTATIVE ID IN SOME CASES CAN PROVIDE DATA OF SAME QUALITY AS LEVELS IV OR V	SIMILAR DETECTION LIMITS TO CLP LESS RIGOROUS QA/QC
RISK ASSESSMENT PRP DETERMINATION EVALUATION OF ALTERNATIVES ENGINEERING DESIGN	LEVEL IV	HPL ORGANICS/INORGANICS BY GC/MS AA, ICP LOW ppb DETECTION LIMIT	TENTATIVE IDENTIFICATION OF NON-HPL PARAMETERS SOME TIME MAY BE REQUIRED FOR VALIDATION OF PACKAGES	GOAL IS DATA OF KNOWN QUALITY RIGOROUS QA/QC
RISK ASSESSMENT PRP DETERMINATION	LEVEL V	NON-CONVENTIONAL PARAMETERS METHOD-SPECIFIC DETECTION LIMITS MODIFICATION OF EXISTING METHODS APPENDIX B PARAMETERS	MAY REQUIRE METHOD DEVELOPMENT/MODIFICATION MECHANISM TO OBTAIN SERVICES REQUIRED SPECIAL LEAD TIME	METHOD-SPECIFIC

- **LEVEL V** - Non-standard methods Analyses which may require method modification and/or development CLP Special Analytical Services (SAS) are considered Level V
- **LEVEL IV** - CLP Routine Analytical Services (RAS) This level is characterized by rigorous QA/QC protocols and documentation and provides qualitative and quantitative analytical data. Some regions have obtained similar support via their own regional laboratories, university laboratories, or other commercial laboratories
- **LEVEL III** - Laboratory analysis using methods other than the CLP RAS This level is used primarily in support of engineering studies using standard EPA approved procedures. Some procedures may be equivalent to CLP RAS, without the CLP requirements for documentation
- **LEVEL II** - Field analysis This level is characterized by the use of portable analytical instruments which can be used on-site, or in mobile laboratories stationed near a site (close-support labs). Depending upon the types of contaminants, sample matrix, and personnel skills, qualitative and quantitative data can be obtained
- **LEVEL I** - Field screening This level is characterized by the use of portable instruments which can provide real-time data to assist in the optimization of sampling point locations and for health and safety support. Data can be generated regarding the presence or absence of certain contaminants (especially volatiles) at sampling locations

Table A1.4
 APPROPRIATE ANALYTICAL LEVELS - BY DATA USE

DATA USE ANALYTICAL LEVEL	SITE CHARACTERIZATION (INCLUDING HEALTH & SAFETY)	RISK ASSESSMENT	EVALUATION OF ALTERNATIVES	ENGINEERING DESIGN OF REMEDIAL ACTION	OTHER
LEVEL I	✓				
LEVEL II	✓		✓		
LEVEL III	✓	✓	✓	✓	
LEVEL IV		✓	✓	✓	
LEVEL V		✓		✓	
OTHER				✓	

NOTE. CHECK APPROPRIATE BOX (ES)

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Table A1.5
 DQO SUMMARY FORM

1 SITE		EPA REGION _____					
NAME _____		PHASE _____					
LOCATION _____		RI 1 RI 2 RI 3 ERA FB RD RA					
NUMBER _____		(CIRCLE ONE)					
2 MEDIA (CIRCLE ONE)	SOL	GW	SW/SED	AIR	SIO	OTHER _____	
3 USE (CIRCLE ALL THAT APPLY)	SITE CHARAC. (H&S)	RISK ASSESS.	EVAL. ALTS.	ENGG DESIGN	PPP DETER.	MONITORING REMEDIAL ACTION	OTHER _____
4. OBJECTIVE _____ _____ _____							
5. SITE INFORMATION							
AREA _____				DEPTH TO GROUND WATER _____			
GROUND WATER USE _____							
SOIL TYPES _____							
SENSITIVE RECEPTORS _____							
6. DATA TYPES (CIRCLE APPROPRIATE DATA TYPES)							
A. ANALYTICAL DATA				B. PHYSICAL DATA			
pH	PESTICIDES	TOX	PERMEABILITY	HYDRAULIC HEAD			
CONDUCTIVITY	PCB	TOC	POROSITY	PENETRATION TEST			
VQA	METALS	STX	GRAIN SIZE	HARDNESS			
ASB	CYANIDE	COD	BULK DENSITY	_____			
TCLP	_____	_____	_____	_____			
7 SAMPLING METHOD (CIRCLE METHOD(S) TO BE USED)							
ENVIRONMENTAL	BIASED	GRAB	NON-INTRUSIVE	PHASED			
SOURCE	GRID	COMPOSITE	INTRUSIVE	_____			
8. ANALYTICAL LEVELS (INDICATE LEVEL(S) AND EQUIPMENT & METHOD(S))							
LEVEL 1 FIELD SCREENING EQUIPMENT _____							
LEVEL 2 FIELD ANALYSIS - EQUIPMENT _____							
LEVEL 3 NON-CLP LABORATORY METHODS _____							
LEVEL 4 CLP/RAS - METHODS _____							
LEVEL 5 NON STANDARD _____							
9. SAMPLING PROCEDURES							
BACKGROUND 2 PER EVENT OR _____							
CRITICAL (LIST) _____							
PROCEDURES _____							
10. QUALITY CONTROL SAMPLES (CONFIRM OR SET STANDARD)							
A. FIELD				B. LABORATORY			
COLLOCATED - 5% OR _____				REAGENT BLANK 1 PER ANALYSIS BATCH OR _____			
REPLICATE - 5% OR _____				REPLICATE 1 PER ANALYSIS BATCH OR _____			
FIELD BLANK - 5% OR _____				MATRIX SPIKE - 1 PER ANALYSIS BATCH OR _____			
TRIP BLANK - 1 PER DAY OR _____				OTHER _____			
11 BUDGET REQUIREMENTS							
BUDGET _____				SCHEDULE _____			
STAFF _____							
CONTRACTOR _____				PRIME CONTRACTOR _____			
SITE MANAGER _____				DATE _____			

FOR DETAILS SEE SAMPLING & ANALYSIS PLAN

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DQO SUMMARY FORM INSTRUCTIONS

- 1. SITE** Identify the site and phase of the work to be conducted
- NAME - Site name or assignment as stated in the WA
 - LOCATION - City or Town County and State where site is located
 - NUMBER - Site number as stated in the WA
 - EPA REGION - EPA Region where the site is located
 - PHASE - Circle work phase for which DQOs are being developed (number sequentially for each phase as appropriate)
 - RI Remedial
 - ERA Expedited Response Action
 - FS Feasibility Study
 - RD Remedial Design
 - RA Remedial Action

- 2. MEDIA** Circle the media being investigated, only one form will be completed for each media.
- SOIL - Surface and subsurface soils
 - GW - Ground water
 - SW/SED - Surface water and sediment (a sediment sample will be taken if possible at each surface water sampling location)
 - AIR - Air quality and respirable dust monitoring
 - BIO - Biological monitoring, flora and fauna
 - OTHER - Indicate other "media" being investigated i.e. buildings, underground conduits, etc.

- 3. USE** Circle the intended use(s) of the data to be developed.
- SITE CHARAC. (HAS) - Site characterization which includes a determination of the level(s) of health and safety protection required at the site
 - RISK ASSESS - Risk assessment, data to be used to perform the endangerment assessment or public health evaluation
 - EVAL. ALTS. - Evaluate alternatives, data will be used to evaluate or screen remedial/technological alternatives
 - ENG'G DESIGN - Data will be used to perform detailed engineering design of remedy
 - MONITORING - Data will be used to monitor during remedy implementation or establish baseline conditions for long term monitoring after site remediation
 - PRP DETERMINATION - Data will be used to confirm/ingest print contaminants to specific potentially responsible parties for possible future or pending enforcement actions
 - OTHER - Indicate other specific data uses

- 4. OBJECTIVE** Provide a concise, specific statement that answers the question "Why am I taking these samples?"

- 5. SITE INFORMATION** Provide the site information necessary to gain an overview of the site and the relative complexity and extent of data requirements
- AREA - Indicate the area of the site in acres and an indication of the configuration (length and width)
 - DEPTH TO GROUND WATER - Indicate the depth to ground water from the ground surface, to the extent known identify seasonal fluctuation and the depth and thickness of multiple aquifers
 - GROUND WATER USE - Identify both potable and non-potable ground water use(s) by aquifer, if appropriate, and the point(s) of extraction relative to the site
 - SOIL TYPES - Identify, to the extent known, the site soil strata and relative depths below ground surface
 - SENSITIVE RECEPTORS - Identify population and environmental concerns, relative to the site, which could be impacted by contaminant migration

- 6. DATA TYPES** Circle the appropriate analytical and physical data required to determine the type, degree, extent and migration characteristics of the contaminants and the remedial site characteristics. The selection of data types required must be developed by the site manager with the data users as described in section 3.2

- 7. SAMPLING METHODS** - Circle the appropriate sampling method(s) to be used in obtaining the required data in accordance with the objectives above
- ENVIRONMENTAL - Refers to media sampling of air, water, soils and the biological environment to determine the extent of contamination
 - SOURCE - Refers to the sampling of the actual contamination source(s)
 - BIASED - Refers to sampling which focuses on a specific site area, characteristic or problem factor based upon site knowledge and/or modeling
 - GRID - Refers to unbiased sampling which provides a representative estimate of contamination problem over the entire site
 - GRAB - Refers to discrete samples which are representative of a specific location at a specific point in time.
 - COMPOSITE - The mixture of a number of grab samples to represent the average properties of the parameters of concern over site extent of the area sampled

- NON-INTRUSIVE - Refers to obtaining data using methods and equipment that do not require the physical extraction of sample from the media being sampled
- INTRUSIVE - Refers to physically extracting samples from the media being sampled
- PHASED - Refers to performing discrete time-phased sampling events and using the information obtained in the previous event to refine the subsequent sampling event

- 8. ANALYTICAL LEVELS** The analytical levels are described in Section 9 of the Guidance

- LEVEL 1 FIELD SCREENING EQUIPMENT - Identify the field monitoring equipment to be used and the manufacturer's specified detection limits when known
- LEVEL 2 FIELD ANALYSIS EQUIPMENT - Identify the field analysis to be used and the historically achievable instrument detection limits
- LEVEL 3 NON-CLP LABORATORY METHODS - Identify the laboratory method(s) to be used and the historically achievable precision and accuracy when available
- LEVEL 4 CLP/RAAS METHODS - Identify the CLP laboratory method(s) to be used and the historically achievable precision and accuracy
- LEVEL 5 NON-STANDARD - Specify requirement for non-standard analysis, analytical procedures to be used and required precision and accuracy

- 9. SAMPLING PROCEDURES** The procedures to be used in obtaining the required samples are to be defined, a description of the critical samples is to be provided and the requirement of obtaining a minimum of two background samples per sampling event is to be confirmed or the deviation from this minimum standard defined

- 10. QUALITY CONTROL SAMPLES** The identified minimum standards for the field and laboratory quality control samples must be confirmed or revised on a site specific basis

- 11. BUDGET REQUIREMENTS** Based upon the analysis summarized above the critical resource requirements shall be defined
- BUDGET - The estimated cost of the sampling and analysis shall be presented in dollars
 - SCHEDULE - The total time required to perform the sampling and the estimated time, as appropriate to perform the analysis shall be presented by calendar days, by phase
 - STAFF - The key staff disciplines required to perform the sampling shall be identified

The form shall identify the contractor directly responsible for the work the prime contractor and must be signed and dated by the site manager

Precision

Precision is a quantitative measure of data quality which refers to the reproducibility or degree of agreement among replicate measurements of a single analyte. The closer the numerical values of the measurements are to each other, the more precise the measurements. One of the methods used to estimate the precision of a method is the standard error of the estimates for the least square regression line of "measured" versus "target" concentrations. The primary role of this application is to characterize the precision of any analysis method under specified conditions. This allows comparison of precision of different results produced by the same method. Analytical precision for a single analyte may be expressed as a percentage of the difference between results of duplicate samples and matrix spike duplicates for a given analyte. Precision may be determined from the results of duplicate and matrix spike duplicate analyses. For example, relative percent difference may be calculated as

$$\text{Precision} = \text{Relative Percent Difference} = \frac{C_1 - C_2}{\frac{C_1 + C_2}{2}} \times 100\%$$

where

- C_1 = Concentration of the analyte in the sample or matrix spike duplicate
- C_2 = Concentration of the analyte in the duplicate/replicate or matrix spike duplicate

During the collection of data using field methods or instrumentation, precision is checked by reporting several measurements taken at one location and comparing the results. Precision shall be reported as the relative percent difference for two results and as the standard deviation for three or more results. Sample collection precision shall be measured in the laboratory with the analysis of field replicates and laboratory duplicates.

Accuracy

Accuracy is a quantitative measure of data quality which refers to the degree of difference between measured or calculated values and the true value. The closer to the true value (concentration), the more accurate the measurement. One of the measures of analytical accuracy is expressed as the percent recovery of a spike or tracer which has been added to the environmental sample at a known concentration before analysis. For example, accuracy may be determined from the results of matrix spike and other appropriate analyses as

$$\text{Accuracy} = \text{Percent Recovery} = \frac{A_F - A_o}{A_r} \times 100\%$$

where

- A_r = Total amount found in spiked sample
 A_o = Amount found in unspiked sample
 A_P = Amount added to sample

Representativeness

Representativeness is a qualitative measure of data quality defined by the degree to which the data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition. If the same results are reproducible, the data obtained can be said to represent the environmental condition. Representativeness is ensured by collecting sufficient samples of an environmental medium, properly chosen with respect to place and time. The methods and protocols used to select samples that are representative of a particular sampling site will be described in the specific WP/FSP/QAA.

Completeness

Completeness is a quantitative measure of data quality expressed as the percentage of valid or acceptable data obtained from a measurement system. The objectives of the field sampling program are to obtain samples for all analyses required at each individual site, to provide sufficient sample material to complete those analyses, and to produce QC samples that represent all possible contamination situations, i.e., potential contamination during sample collection, transportation, or storage. The goal of completeness for data packages is 100 percent, however, this is not a requirement.

For example, one equation used to calculate percent completeness is:

$$\text{Completeness} = DP_v = \frac{DP_t - DP_i}{DP_t} \times 100\%$$

where.

- DP_v = Valid or acceptable data points
 DP_i = Invalid data point (sum of the percent recovery values outside project or laboratory control limits and number of contaminants in blank samples)
 DP_t = Total number of QC data points (e.g., each volatile organic compounds [VOC] analysis is equal to 34 data points, each semivolatile analysis is equal to 65 data points, each pesticide/PCB analysis is equal to 27 data points, each metals/cyanide analysis is equal to 29 data points, each field and inorganic analysis is equal to 1 data point, and each radiochemistry analysis is equal to 1 data point per analysis).

Comparability

Comparability is a qualitative measure defined by the confidence with which one data set can be compared to another. Differences in field and laboratory procedures greatly affect comparability. To optimize comparability, only the specific methods and protocols that have been selected or specified as appropriate for ER activities shall be used to collect and analyze samples. By using carefully selected sampling and analysis procedures, data sets can be comparable at each specific site at the RFP and between sites.

STAGE 3 - DESIGN DATA COLLECTION PROGRAM

The major elements of Stage 3 are

- o Assembly of data collection components
- o Development of data collection documentation

These stages are shown in Figure A1 6

ASSEMBLE DATA COLLECTION COMPONENTS

The intent of Stage 3 is to compile the information and DQOs developed for specific tasks in Stage 2 into a comprehensive data collection program. A detailed list of all samples to be collected should be assembled in a format that includes.

- o phase
- o media
- o sample type
- o number of samples
- o sample location
- o analytical methods
- o QC samples (type and number)

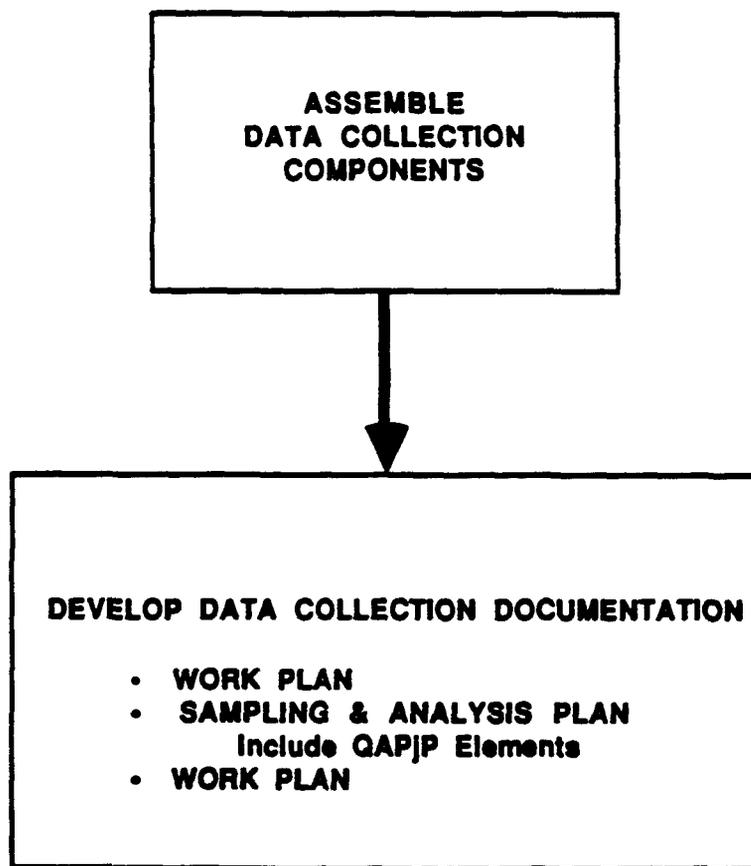
DEVELOP DATA COLLECTION DOCUMENTATION

The output of the DQO development process is a well defined WP/FSP with summary information provided in the QAA.

The DQO process provided here does not require the submittal of deliverables in addition to those already established in the regions. Rather, the DQO process provides a framework to ensure that all the pertinent issues related to the collection of data with known quality are addressed.

DQOs will be developed in the WP/FSPs and will be summarized in the QAAs. Once the DQOs have been established, they are reviewed by EMAD to determine analytical needs and laboratory availability. EMAD will also determine if the existing validation guidelines are appropriate and whether or not they will need to be expanded.

**FIGURE A1.6
DQO STAGE 3 ELEMENTS**



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APPENDIX B
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